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PART III

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

■

FILLED MILK PRODUCTS; MILK, CREAM, AND CHEESE SUBSTITUTES; SKIM MILK CHEESE FOR MANUFACTURING; AND CHEESE AND RELATED CHEESE PRODUCTS

Identity Standards

[4110-03]

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

[21 CFR Part 102]

[Docket No. 78N-0090]

FILLED MILK PRODUCTS; COMMON OR USUAL NAME

Withdrawal of Proposal and Termination of Rulemaking Proceedings

AGENCY: Food and Drug Administration.

ACTION: Withdrawal of proposal.

SUMMARY: The Food and Drug Administration is withdrawing the proposal to establish a common or usual name for filled milk products and is terminating the rulemaking proceeding. The proposal would have established by regulation a common or usual name for filled milk products. The Commissioner of Food and Drugs is proposing elsewhere in this issue of the FEDERAL REGISTER a standard of identity for milk and cream substitutes and cheese substitutes.

EFFECTIVE DATE: This action is effective September 19, 1978.

FOR FURTHER INFORMATION CONTACT:

Eugene T. McGarrahan, Bureau of Foods (HFF-415), Food and Drug Administration, Department of Health, Education, and Welfare, 200 C Street SW., Washington, D.C. 20204, 202-245-1155.

SUPPLEMENTARY INFORMATION: Under the U.S. district court decision in *Milnot Co. v. Richardson*, 350 F. Supp. 221 (S.D. Ill., 1972), holding the Filled Milk Act unconstitutional, the Commissioner concluded that appropriate labeling for filled milk products should be promptly considered and a regulation promulgated to govern the common or usual name of these products. Accordingly, a proposal to amend part 102 (21 CFR 102) by adding new § 102.18 to establish a common or usual name for filled milk products was published in the FEDERAL REGISTER of August 2, 1973 (38 FR 20748). Interested persons were invited to comment particularly on the suitability and meaning of the word "filled" in the name of the food.

A total of 250 comments were received in response to the proposal. Of this total, 233 comments either opposed adoption of the proposal as published or questioned the advisability of promulgating regulations governing the common or usual name of these products, and 17 comments favored the proposal as published or on condition that it provide for proof of nutritional equivalency. Stating that the meaning of the word "filled" is not comprehensible and could mislead consumers, 192 comments opposed the use of the term in the name of the food. They also opposed the use of the words "milk" and "cream" in the name of the food because of possible consumer confusion with the traditional product. Six comments favored the terminology as set out in the proposal. Twenty-one comments considered filled milk products to be imitation milk products which should be so labeled. Fourteen comments suggested using names with prefixes such as "mello" or suffixes such as "ine," as in various State regulations for non-milkfat-based products. Also suggested were names such as "modified," "blend," "blended," "substitute," "vegetable fat drink," and "nondairy product."

Since publication of the filled milk products proposal, the Commissioner has observed that many new substitute dairy foods, including cheese substitutes, have been marketed. These foods are made to resemble standardized dairy foods by complete or partial replacement of milkfat and/or milk protein with vegetable fats and proteins. Because the filled milk products proposal provides for the replacement of only milkfat with any fat or oil other than milkfat and does not mention milk protein, it lacks the provisions necessary for regulation of all of the new substitute dairy foods.

Therefore, in view of the adverse comments received on the proposal, and because it does not contain provisions consistent with those necessary for regulation of various other substitute dairy foods, the need for which is demonstrated by recent industry petitions to establish a standard of identity and/or a common or usual name regulation for cheese substitutes, the Commissioner concludes the proposal to establish a common or usual name for filled milk products is no longer necessary and rulemaking proceedings on the matter are terminated.

The Commissioner is proposing elsewhere in this issue of the FEDERAL REGISTER a standard of identity for milk and cream substitutes and cheese substitutes providing for both fat and protein replacement.

This action is taken under the Federal Food, Drug, and Cosmetic Act (secs. 401, 701, 52 Stat. 1046, 1055-1056, as amended, 70 Stat. 919, 72 Stat. 948 (21 U.S.C. 341, 371) and under authority delegated to the Commissioner (21 CFR 5.1)).

Dated: September 8, 1978.

JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-25818 Filed 9-18-78; 8:45 am]

[4110-03]

[21 CFR Parts 131 and 133]

[Docket No. 75P-0121]

SUBSTITUTES FOR MILK, CREAM, AND CHEESE

Standards of Identity

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: This proposal would establish standards of identity for milk and cream substitutes and cheese substitutes. The proposed standards of identity would (1) establish descriptive names for milk and cream substitutes, and cheese and cheese product substitutes, (2) permit the use of any safe and suitable optional ingredients in their formulation, (3) establish compositional requirements including requirements for nutritional equivalence to the foods which they simulate, and (4) establish appropriate labeling requirements. These standards of identity are being proposed because of the introduction of many new dairy food substitutes and in response to petitions from the cheese industry. Any regulation issued on the basis of this proposal will reflect the Commissioner's consideration of relevant information presented at the food labeling hearings announced in the FEDERAL REGISTER of June 9, 1978.

DATES: Comments by November 27, 1978. Proposed compliance for products initially introduced into interstate commerce: One year after the date of issuance of a regulation.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Room 4-65, 5600 Fishers Lane, Rockville, Md. 20857.

FOR FURTHER INFORMATION CONTACT:

Eugene T. McGarrahan, Bureau of Foods (HFF-415), Food and Drug Administration, Department of Health, Education, and Welfare, 200 C Street SW., Washington, D.C. 20204, 202-245-1155.

SUPPLEMENTARY INFORMATION: The Commissioner of Food and Drugs, on his own initiative, proposes to establish definitions and standards of identity for milk and cream substitutes (foods made in semblance of standardized milk and cream foods). He also proposes to establish, on his own initiative and in consideration of petitions from the National Cheese In-

stitute, 110 North Franklin Street, Chicago, Ill. 60606; Anderson Clayton Foods Co., One Main Place, Dallas, Tex. 75250; and Fisher Cheese Co., Wapakoneta, Ohio 45895, definitions and standards of identity for cheese and cheese product substitutes (foods made in semblance of cheese, cheese products, pasteurized process cheese, and pasteurized process cheese products).

The Commissioner has observed that many new dairy food substitutes, made in semblance of standardized dairy foods, have been introduced in markets recently. This increase in dairy food substitutes is due in part to a relaxation of restrictions on such foods since (1) the Filled Milk Act of 1923 (42 Stat. 1486), 21 U.S.C. 61-64, was declared unconstitutional by the U.S. District Court for the Southern District of Illinois in *Milnot Co.* v. *Richardson*, 350 F. Supp. 221 (S.D. Ill., 1972) and (2) the Filled Cheese Act of June 6, 1896 (29 Stat. 253) (26 U.S.C. 4831-4836) was repealed on October 6, 1974, by the 93d Congress (88 Stat. 1466).

The repeal of the Filled Cheese Act and the Filled Milk Act was recommended by the White House Conference on Food, Nutrition, and Health in December 1969. Consumers had expressed the desire for modified milk and cheese foods made with vegetable fats, but the development of such foods was inhibited by the restrictive nature of these acts.

The Filled Milk Act prohibited the shipment of any filled milk or cream in interstate commerce. The Filled Milk Act defined "filled milk" as "any milk, cream, or skimmed milk, whether or not condensed, evaporated, concentrated, powdered, dried or desiccated, to which has been added, or which has been blended or compounded with, any fat or oil other than milkfat, so that the resulting food is in imitation or semblance of milk, cream, or skimmed milk, whether or not condensed, evaporated, concentrated, powdered, dried, or desiccated." This definition, however, was not intended to include any distinctive proprietary food compound which would not be readily mistaken in taste for milk or cream, or where such food was intended for feeding infants and young children.

By taxing the filled cheese and its producers and distributors, the Filled Cheese Act, which was administered by the Internal Revenue Service, sought to control and identify filled cheeses made in semblance of natural cheese. The Filled Cheese Act defined filled cheese as "all substances made from milk or skimmed milk, with the admixture of butter, animal oil or fats, vegetable, or any other oils or compounds foreign to such milk and made in imitation and semblance of cheese."

As a result of the repeal of the filled Cheese Act and the declaration of the Filled Milk Act as unconstitutional, filled cheese foods and filled milk foods are now subject solely to provisions of the Federal Food, Drug, and Cosmetic Act and the Fair Packaging and Labeling Act and move freely in interstate commerce as nonstandardized foods. In view of the change in the regulatory status of these foods and the recent increase in sales of dairy food substitutes, the Commissioner believes that the establishment of standards of identity for these and other foods made in semblance of standardized milk, cream, cheese, and foods made of cheese, will promote honesty and fair dealing in the interest of consumers.

Milk and Cream Substitutes

The Commissioner of Food and Drugs published in the Federal Register of May 18, 1968 (33 FR 7456) a notice of proposed rulemaking to establish standards of identity and quality for imitation milks and creams. Based on comments received in response to that proposal, a revised proposal that was limited to imitation milks was published in the Federal Register of October 9, 1969 (34 FR 15657). All comments received in response to this second proposal were opposed to adoption of the proposal as published. In addition the Commissioner became aware that the production of imitation milks was declining. The Commissioner, therefore, concluded that standards should not be established at that time and a notice of withdrawal of the October 9, 1969, proposal was published in the Federal Register of June 3, 1970 (35 FR 8584).

A third proposal to regulate milk substitutes was published in the Federal Register of August 2, 1973 (38 FR 20748). The proposal sought to establish the common or usual name, "filled ——," for the foods defined by the Filled Milk Act, the blank being filled in with the name of the counterpart milk or cream food as designated in part 131 (21 CFR Part 131). Comments on this proposal suggested that the term "filled" in "filled milk" is meaningless to most consumers and that it might be misleading by implying that something is missing in the traditional dairy food and that the "filled" dairy food is more complete. In view of these and other relevant comments, that proposal is being withdrawn. A notice of withdrawal of that proposal appears elsewhere in this issue of the Federal Register.

The Commissioner has reviewed the comments submitted in response to the imitation milk and filled milk proposals and he is proposing to establish a definition and standard of identity which will govern the composition and labeling of milk and cream substitutes. The Commissioner has observed the market and notes that many new dairy food substitutes are being sold with potentially misleading labeling. Many of these substitutes bear fanciful names while others have adopted "imitation" dairy food labeling. Also, some milk and cream substitute foods contain partial or total milk protein replacements as well as milkfat replacements. The Commissioner believes that a standard of identity that would encompass both types of substitutes should be established for these foods. Accordingly, he is proposing to establish such a standard in new § 131.300 Milk and cream substitutes as set out below.

Cheese Substitutes

The Commissioner of Food and Drugs has received three petitions from representatives of the cheese industry proposing the establishment of regulations to govern the nomenclature, composition, and labeling of cheese substitutes. He has also received two letters of comment suggesting common or usual names for these foods. A brief summary of these petitions and comments follows. The petitions and letters of comment are on file with the Hearing Clerk, Food and Drug Administration, Room 4-65, 5600 Fishers Lane, Rockville, Md. 20857.

The National Cheese Institutes (NCI), 110 North Franklin Street, Chicago, Ill. 60606, submitted a petition dated June 10, 1975 (docket No. 75P-0121) proposing the establishment of a standard of identity for cheese analogs under the name "Golana" in part 133 (21 CFR Part 133). The NCI petition stated that the name "Golana" was selected because it was pleasant sounding, easily pronounced, and not related to another food. Golana is also "analog" spelled backward. The NCI rejected the word "cheese" as a root word on the ground that such terms might be confused with names of natural cheeses. Further, NCI suggested that the word "analog" was more applicable than words such as "alternate," "substitute," or "imitation," because analog connotes something having properties corresponding to something else, but different in origin. "Imitation," the petition noted, already has been defined in the Code of Federal Regulations and would connote nutritional inferiority, while "substitute" or "alternate" suggests the food is intended to serve in place of another. The NCI petition argued that these foods should stand on their own merits and not ride on the coattails of the foods which they simulate.

Briefly, the petition for the standard of identity for Golana defines a cheese

analog as the food made in semblance of cheese or a cheese product in which safe and suitable nonmilk ingredients supplement or replace any or all nutritive milk components. The proposed standard would also establish nutritional equivalency requirements for Golana and a system of nomenclature for Golana-type foods based on the degree of semblance to the cheese simulated, including its nutritional equivalency to that food. For example, a Golana simulating mozzarella cheese that conforms to the organoleptic and physical properties, as well as to the established fat and moisture requirements for mozzarella cheese, and contains the required levels of protein and nutrients proposed in the standard of identity for Golana would be named "Golana mozzarella cheese analog." A cheese analog that does not conform to the organoleptic and physical properties, and the fat and moisture requirements for a specific cheese variety, but is nutritionally equivalent to cheddar cheese, would be named simply "Golana cheese analog." However, a food that conforms to the organoleptic and physical properties of a cheese analog, but fails to conform to the organoleptic and physical properties and the compositional requirements of a specific cheese variety, and is not nutritionally equivalent to cheddar cheese would be named "Imitation Golana."

The Anderson Clayton Foods Co., One Main Place, Dallas, Tex. 75250, submitted a petition dated August 13, 1975 (docket No. 75P-0233) proposing the establishment of a common or usual name regulation for cheese substitutes in 21 CFR Part 102, under the name "Cheesana Cheese Substitutes." A second petition dated November 28, 1975 (docket No. 75P-0354) proposing the establishment of a common or usual name regulation for these foods under the name "Cheese and cheese product substitutes" was submitted by the Fisher Cheese Co., P.O. Box 409, Wapakoneta, Ohio 45895. Both firms manufacture cheese substitute-type foods. In both petitions, the proposed common or usual names would reference the type of standardized or recognized cheese variety simulated, e.g., "Cheesana Cheddar Cheese Substitute" or "Cheddar Cheese Substitute," followed by an informative statement defining the distinguishing characteristic of the food such as "contains vegetable oil." Both petitions recommended establishing nutritional equivalency requirements for cheese substitutes but neither would require that the cheese substitute conform to the established fat and moisture requirements of the cheese being simulated.

Two letters from industry representatives suggested common or usual names for cheese substitutes. One comment stated that the name should inform the consumer of the basic nature of the substitute. The comment further suggested the use of a phrase such as "Highly Polyunsaturated Filled —— Cheese" be adopted for filled cheeses which provide a minimum of 30 percent polyunsaturates of total fats, with a total polyunsaturated/saturated fat ratio of at least 1:1 and maximum cholesterol level of 15 milligrams/100 grams product. Filled cheeses which do not meet these standards would simply be designated as "Filled —— Cheese." In both cases, the blank would be filled in with the type of filled cheese, e.g., "cheddar." The second comment suggested that names such as "nondairy imitation cheese" or "nondairy cheese replacement" be used instead of a contrived or arcane name that would be confusing to consumers and that would require extensive advertising to establish the food's identity.

The Commissioner has considered both comments and has decided that the names suggested would not be generally applicable to all types of cheese substitutes. As indicated above, the use of the term "filled" to refer to substitutes containing replacements for milkfat may be confusing to consumers and may cause some consumers to think filled dairy products are superior to traditional dairy products. The suggested phrase "Highly Polyunsaturated Filled —— Cheese" could imply tht the food is a special dietary food. Nomenclature for special dietary foods is beyond the scope of this proposal. The names "nondairy imitation cheese" and "nondairy cheese replacement" would not accurately describe the nature of all cheese and cheese product substitutes since many substitutes use milk solids and milk derived ingredients, such as casein, whey or modified whey, milkfat, or lactose as components of the food.

Standards of Identity Versus Common or Usual Name Regulations

Both standards of identity and common or usual name regulations establish the name of the food, which identifies and describes the food's basic nature. In addition to establishing the name of the food, the common or usual name regulation may require that the name of the food include the percentage of any characterizing ingredient when the proportion of such ingredient has a material bearing on the price or when the label or appearance of the food may otherwise create an erroneous impression that such ingredient is present in an amount greater than is actually the case. The intended purpose is to provide consumers with relevant information about an important aspect of the food's composition in the labeling so that informed purchasing decisions can be made.

In addition to providing for informative labeling, standards of identity provide a further measure of consumer protection by defining the composition of the food, prescribing the mandatory ingredients as well as the optional ingredients, and establishing the amounts or relative proportions of these ingredients in the food. Most standards of identity require that the common or usual name of all optional ingredients be declared on the label unless exempted by the Federal Food, Drug, and Cosmetic Act or by other regulations. Standards of identity are established to promote honesty and fair dealing in the interest of consumers. They serve to eliminate confusion in those cases where it would be difficult for the consumer to determine, solely on the basis of informative labeling, the relative merits of a variety of products superficially resembling one another.

The standards of identity governing natural cheeses do not provide for variations from the established levels or ranges of minimum fat and solids content or the maximum allowable moisture content, although these standards may allow for variations in the manufacturing process as long as the resultant cheese exhibits the same physical and chemical properties. The composition of the ingredients, the types of organisms used, and the manufacturing process contribute to the uniqueness of a given cheese variety. The differences in total and relative amounts of fat, milk solids-not-fat, and moisture present in cheese ingredients are basic reasons that one cheese variety is distinct from another. Each natural cheese standard of identity thus insures the integrity of the natural cheese by setting limits on its fat, milk solids-not-fat, and moisture content.

Common or usual name regulations would not restrict the composition of cheese substitutes, except as is required for nutritional content. Manufacturers would be free to vary the fat content of these foods to suit consumer's preferences and pocketbooks. In a nationwide survey of consumers conducted by the U.S. Department of Agriculture, "Homemakers' Opinions on Dairy Products and Imitation Foods" (Marketing Research Report No. 995, May 1973), the majority of the homemakers polled thought that, generally, imitation foods were cheaper, contained fewer calories, were more convenient and easier to use, and had better keeping characteristics than genuine dairy foods. The majority also felt that genuine dairy foods had superior taste, food value, and purity or absence of additives compared to the imitation.

Hence, cheese substitutes, if regulated by a common or usual name regulation as petitioned for by Fisher Cheese Co. or by Anderson Clayton Foods, might not be inconsistent with consumer expectations. This could be so even though such cheese substitutes would not have to meet fat content requirements or possess the same organoleptic and physical characteristics as the standardized cheese, provided that the cheese substitutes cost less and effectively served the purposes for which they were designed. Further, absence of specific compositional requirements would allow more flexibility in developing new cheese substitutes.

A common or usual name regulation could require that the amount and type of protein and fat in the substitute food be included in the labeling. These foods also would be required to bear nutritional labeling. With such labeling supplementing an appropriate product name, it is doubtful that these foods would be mistaken for genuine dairy foods. However, each of these requirements also may be accomplished by standards of identity.

A standard of identity such as that petitioned for by NCI could include a requirement that the moisture, solids, and fat values for the substitute food be equivalent to those of the food being simulated. This compositional requirement would assure the consumer of uniformity of composition and would prevent the debasement of foods as costs of ingredients increase.

The adoption of a standard of identity also would serve a regulatory function. Consumers' ability to distinguish one cheese variety from another or one food made with cheese from another by taste and sight varies because the determination is subjective. The only objective, practical way to determine whether a specific cheese variety or specific food made with cheese is properly labeled as to variety or type is to analyze the food for fat, solids, and moisture content. With such objective analyses and subjective organoleptic evaluations, a regulatory agency can make a determination concerning label claims.

A standard of identity for cheese substitutes would also be more consistent with the ongoing revisions of part 133 (21 CFR Part 133). In the FEDERAL REGISTER of October 4, 1977 (42 FR 53970) the Commissioner published a proposal that would revise the current pasteurized process cheese, cheese food, and cheese spread standards of identity and group them into two categories—process cheese and cheese products.

Under that proposed revision, all pasteurized process cheeses would remain in one standard of identity category and retain their current nomenclature except that use of the term "pasteurized" in the name would be optional. All pasteurized process cheese foods and pasteurized process cheese spreads, which are generally distinguished from pasteurized process cheese by their lower fat and solids and higher moisture contents, would be grouped into a second category—"pasteurized process cheese products." The terms "pasteurized" and "process" in the names of pasteurized process cheese products would be optional. The proposed revision would require label declaration of the percent of milkfat contained in process cheese and process cheese products. In that proposal the Commissioner reasoned that closely related foods differing primarily in percent of fat and moisture could best be identified by labeling the percentage of fat rather than by different names, such as "food" or "spread." The proposed revision would also require nutritional and complete ingredient labeling.

A similar labeling approach would be equally appropriate for cheese substitutes. A standard of identity for cheese substitutes, as well as one for milk and cream substitutes, could require label declaration of the percent and type of fat used and/or the type of protein ingredients used in the food if other than milk protein. In addition, the standards of identity could be sufficiently flexible to allow for some variability within the compositional requirements. Thus, the standards of identity for the substitutes could establish moisture, solid, and fat content requirements consistent with the standards of identity for the foods they simulate, yet allow for variations in those compositional requirements, within limits, established in the standards, and/or with required label declaration.

The provision permitting the composition of certain foods to vary within certain limits appears in several standards of identity although label declaration may not always be required. Although most cheese standards of identity include minimum levels of fat and solids, the standards of identity for part-skim cheese foods and Neufchatel cheese permit the fat content to vary within a specified range. Further, in view of trends indicating consumer preferences for low fat dairy foods, and the need for economical, yet nutritious foods, it seems only logical to permit the fat content of cheese substitutes to differ from that of the standardized foods they simulate, as long as consumers are not misled.

Establishing a standard of identity for cheese substitutes with adequate requirements for label declaration of ingredients in part 133 (21 CFR Part 133) is a logical extension of the proposed revision of the process cheese and cheese products standards of identity. This approach would keep all nomenclature specifically identifiable with cheese type foods together in one part of the Code of Federal Regulations. Moreover, in view of the fact that dairy foods generaly are regulated by standards of identity, it would seem reasonable to regulate vegetable fat substitutes for these foods in a like manner. The Commissioner maintains that this approach is least disruptive and most consistent with current regulations and policies. Similarly, a standard of identity for mild and cream substitutes could be established in part 131 (21 CFR Part 131) with the standards of identity for milk and cream. Standards of identity for these dairy foods are generally preferred by indusdty and have served the public well for many years. A consistent and systemized regulatory approach to one general type of food lends itself to better understanding and acceptance by industry and the public. Accordingly, the Commissioner concludes that standards of identity for milk, cream, and cheese substitutes will promote honesty and fair dealing in the interest of consumers.

OTHER REQUIREMENTS

The three petitions for cheese substitutes indicate an intent to utilize the name of the standardized food being simulated as part of the name of the substitute food. The Commissioner has considered the use of the names of specific cheese varieties in the names of cheese substitutes. He believes such use appears reasonable and would promote honesty and fair dealing in the interest of consumers. This is particularly true if broad compositional requirements for nutritional equivalency are established for cheese substitutes as set out in this proposed rule. If broad compositional requirements (e.g., moisture and fat levels) as well as requirements are not applied, consumers could find that a certain food claiming to be a substitute for a specific cheese or cheese product does not resemble that food in physical attributes or composition.

The Commissioner maintains that, if the name of the substitute food includes the name of the traditional food it simulates, the substitute food should be reasonably similar to the traditional food. Thus, the substitute food should be nutritionally equivalent to the traditional food and should have similar levels of fat and moisture, as well as similar physical attributes such as color, body, and texture. The Commissioner is aware that regardless of the fat and moisture content, the flavor and texture of cheese substitutes would probably differ in some respects from natural cheeses because vegetable fats and proteins have their

own unique organoleptic properties. However, a requirement for similarity would insure that the characteristics of the cheese substitute resemble those of the traditional food used in the name of the cheese substitute.

NOMENCLATURE

A scheme for establishing the nomenclature for cheese substitutes is shown in the chart below. The scheme provides for: (1) Cheese substitutes that comply with the compositional requirements for fat and moisture content of the cheeses which they simulate, and (2) those that do not comply with the established fat and moisture contents of such cheeses. The name of the cheese substitute that conforms to the required fat and moisture levels for a standardized cheese product simulated would consist of the name of the cheese simulated followed by the term "substitute." In the case of a cheese substitute that does not conform to the established fat and moisture levels for the cheese simulated, the name of the food would consist of the name of the cheese simulated followed by the terms "product substitute." The term "product" is used to indicate a variation in the fat content and is consistent with the use of the term in the proposed pasteurized process cheese standards revision. In addition, a declaration of the type of fat contained and the percent by weight of the total fat in the cheese substitute would be required in the name of the substitute. Further, the Commissioner proposes that the name be accompanied by an additional statement, as applicable, which identifies other nonmilk ingredients used to replace milk protein in the manufacture of the cheese substitute.

The Commissioner notes that the declaration of the percent of milkfat in cheeses is not required by the standards of identity for most cheeses. However, he believes that the declaration of the percent of fat in cheeses is of interest to consumers for comparison purposes and is recommending that these foods be labeled with the percent of milkfat by weight contained in the food. He further notes that the declaration of the percent of milkfat will trigger nutritional labeling of the product in accordance with § 101.9(a) (21 CFR 101.9(a)) of this chapter. The proposed system of nomenclature in the chart below incorporates this recommendation for declaration of the percent of milkfat in natural cheeses, as well as certain provisions of the proposed revisions in the nomenclature of the pasteurized process cheese and pasteurized process cheese foods and spreads.

The proposed regulation would require that cheese substitutes that are nutritionally inferior to the cheese which they simulate be labeled with the term "imitation," in accordance with section 403 of the act and § 101.3(e) (21 CFR 101.3(e)) of the regulations. The proposed system of nomenclature would provide adequately for cheese substitutes already being marketed. Further, it would eliminate the need for manufacturers to alter formulations of existing foods in order to comply with the required fat and moisture levels in standarized cheese and cheese products.

Cheese Substitutes Nomenclature Based on Consideration of Composition

Standardized cheese	Cheese substitute
——cheese——pct fat.	——cheese substitute——pct vegetable fat and milkfat.
The first blank is filled in with the name of the standardized cheese variety and the second blank is filled in with the percent of milkfat in the cheese. Declaration of percent fat is recommended but not required unless stated in the standard of identity for the cheese.	The first blank is filled in with the name of the cheese being simulated, if it meets the fat and moisture requirements of the standardized food. The second blank is filled in with the percent of fat in the cheese substitute.
For example: Cheddar cheese 30 pct milkfat.	For example: Cheddar cheese substitute, 30 pct vegetable fat and milkfat.
Pasteurized process cheese——pct fat.	Pasteurized process cheese substitute——pct vegetable fat and milkfat. The blank is filled in with the percent of fat in the food.
For example: Pasteurized process cheese, 33 pct milkfat.[1]	For example: Pasteurized process cheese substitute, 33 pct vegetable fat and milkfat.[1]
——cheese product.	——cheese product substitute.
——pct milkfat.	——pct vegetable fat and milkfat.
The first blank is filled in with the name of the standardized food when the fat and moisture content requirements are optionally variable, or when the fat and moisture content varies from that of the standardized food. The word "product" in the name further indicates that a compositional variation exists.	The first blank is filled in with the name of the food simulated and the second blank is filled in with the percent of fat in the food.
For example: Pasteurized process cheese product, 10 pct milkfat.[2]	For example: Pasteurized process cheese product substitute, 10 pct vegetable fat and milkfat.[2]

[1] Use of the term "pasteurized" is optional.
[2] Use of the terms "pasteurized" and "process" is optional.

The Commissioner maintains that the requirements for the composition of cheese substitutes should remain flexible as long as the foods are formulated from safe and suitable ingredients. However, a cheese substitute should be nutritionally equivalent to the food simulated.

This proposal defines nutritional equivalence for cheese substitutes which are intended to substitute for cheeses and cheese products. The Commissioner believes that it would be impracticale to establish nutrient profiles for each food for which a cheese substitute may be developed. Consequently this proposal identifies the nutritional qualities in terms of vitamins, minerals, and protein content and quality, which must be met in cheese substitutes simulating cheeses that fall into one of four categories of cheese and cheese products. The proposed categories, the first three of which are based upon the average protein levels and the other on minimum protein levels present in the foods comprising the categories, are: (1) Cream cheese (Neufchatel cheese and cream cheese), 8–10 percent protein, 9 percent average; (2) cottage cheese (cottage cheese, lowfat cottage cheese, and dry curd cottage cheese), 12–17 percent protein, 14 percent average; (3) all other natural cheeses (e.g., bleu, cheddar, gruyere, mozzarella, swiss, etc.), 19–30 percent protein, 24 percent average; and (4) process cheese, 23 percent minimum protein, and cheese products (process cheese food, process cheese spread, and natural cheese products which do not comply with established fat and moisture contents), 16 percent protein and higher levels, 16 percent minimum. The protein values were calculated from data obtained from U.S. Department of Agriculture Handbook No. 8-1, "Composition of Foods. Dairy and Egg Products. Raw, Processed, Prepared," 1976. The minimum value used for cheese products is based on the protein content for process cheese spreads which have a lower protein content than process cheese foods. Since this category will also encompass cheese substitutes which simulate other natural cheeses but which may exceed the maximum moisture content of the standardized cheese and which would contain a

lower percent of total solids, this lower protein content, 16 percent, is being proposed as appropriate for this category of foods. The Commissioner specifically requests information on the appropriateness of this minimum protein requirement for cheese product substitutes, since data on cheese products are limited. Further, in order for substitutes to maintain nutritional equivalence to the cheese or cheese product simulated, the proposed regulation includes a requirement for the nutritional quality of the protein used in the formulation of the substitute foods. If the cheese or cheese product substitute is made with milk protein or protein of vegetable origin, the protein efficiency ratio (PER) must be at least 100 percent that of casein.

The proposed vitamin and mineral requirements for cheese and cheese product substitutes have been based primarily on average values for the various cheeses in each category and are expressed in terms of amounts of these nutrients per gram of protein to be contained in the food. For the most part, these vitamins and minerals are those which are present in measurable amounts, i.e., in amounts equal to or greater than 2 percent of the U.S. recommended daily allowance (U.S. RDA) for that nutrient in a 1-ounce serving of the cheese.

Vitamin A has been included in the nutrient profiles for all cheese and cheese product substitutes except cottage cheese type products. Vitamin A is not present in lowfat and dry curd cottage cheese in measurable amounts. A serving of cottage cheese, however, contains approximately 3½ percent of the U.S. RDA for vitamin A. In using the averaging concept for establishing nutrient levels (i.e., the average of the values for a nutrient for the foods comprising a particular category), the average value for vitamin A for cottage cheese type products is less than 2 percent of the U.S. RDA. Hence, no requirement for vitamin A has been included in the cottage cheese nutrient profile. Similar calculations were used to determine the proposed requirements for other nutrients, such as riboflavin, pantothenic acid, vitamins B_6 and B_{12}, folacin, calcium, phosphorus, and zinc.

A requirement for zinc has been included in all of the nutrient profiles for cheese substitutes except cream cheese. These are 0.03 mg zinc for cottage cheese, 0.10 mg for process cheese and natural cheeses, and 0.15 mg for cheese products, provided the cheese substitutes are made with milk protein. If the protein component in the cheese substitute is primarily of vegetable origin, the proposed zinc requirement is twice the proposed requirement for substitutes made with milk protein. The increased level of zinc is necessary because the presence of phytate and other mineral-binding components in foods made from protein of vegetable origin decreases the bioavailability of zinc.

The phosphorus content of process cheese and cheese products is normally higher than that of natural cheese because of the phosphate-containing emulsifiers which may be used in their manufacture. Consequently, a higher level of phosphorus has been proposed for nutritional equivalence for cheese substitutes simulating process cheese and process cheese products.

Although no U.S. RDA has been established for potassium, this nutrient has been included in the nutrient profiles for cottage cheese and for the milk foods. Potassium occurs at significant levels in these foods and is essential for human nutrition. The Commissioner maintains that milk and cottage cheese substitutes should provide levels of potassium consistent with those in milk and cottage cheese. The proposed levels for potassium have been based on data obtained from U.S. Department of Agriculture Handbook 8-1.

Nutrient profiles are proposed for six categories of milk foods. Four of these categories differ primarily by the fat content of the class of foods, i.e., whole milk, lowfat milk, skim milk, and cream. Separate categories were established for sweetened condensed milk and cultured buttermilk because certain nutrients present in the other four categories are not present in sweetened condensed milk or cultured buttermilk at the level of 2 percent of the U.S. RDA per serving or portion of those foods. Those nutrients which are not present in measurable amounts in these foods are vitamin C, niacin, vitamin B_6, and folacin in a 1-fluid-ounce portion of sweetened condensed milk and folacin and vitamin A in a one-cup portion of cultured buttermilk.

The Commissioner proposes that, where a standard of identity for a substitute for milk food contains provisions for the required or optional addition of vitamin A and/or vitamin D, such provisions will be consistent with the provisions for the addition of vitamin A and/or vitamin D in the standard of identity for the food simulated.

Vitamin A is the only nutrient in cream foods which is present at a level of 2 percent of the U.S. RDA. Hence the proposed nutrient profile for cream foods provides for a minimum level of vitamin A in International Units of vitamin A per gram of fat. The other nutrient profiles for milk foods express the requirement for vitamin A in grams of protein present in the food.

The proposed protein levels for milk food substitutes are based on average protein levels for milk foods obtained from U.S. Department of Agriculture Handbook 8-1. If the milk food substitute is made with milk protein and/or protein of vegetable origin, the protein efficiency ratio (PER) of the finished food must be equal to that of milk, i.e., 108 percent of that of casein (Chapman, D. G., Raul Castillo, and J. A. Campbell, "Evaluation of Protein in Foods," "Can. J. Biochem. Physiol.," 37, 679 (1959)). No attempt has been made to provide for protein fortified lowfat milk and skim milk substitute foods. However, manufacturers may increase protein levels in these substitute foods consistent with provisions in the standards of identity for lowfat milk in § 131.135 (21 CFR 131.135) and for skim milk in § 131.145 (21 CFR 131.145).

Having considered the comments received on cheese and cheese product substitutes and present marketing trends of new dairy product substitutes, the Commissioner believes that the establishment of standards of identity for milk and cream substitutes in new § 131.300 and cheese substitutes in new § 133.300 will promote honesty and fair dealing in the interest of consumers.

In a notice published in the FEDERAL REGISTER of June 9, 1978 (43 FR 25296), the Food and Drug Administration, the U.S. Department of Agriculture, and the Federal Trade Commission announced a series of five public hearings to discuss several issues related to food labeling, including ingredient labeling, nutrition labeling, and imitation foods. The last of these hearings is scheduled for October 25-26, 1978. Because the Commissioner intends to take into consideration all relevant information presented at the hearings in developing a regulation based upon this proposal, the Commissioner has scheduled the comment period on this proposal to extent beyond the last of the hearings; comments may be submitted on or before November 27, 1978.

The Commissioner proposes that all products initially introduced into interstate commerce on or after 1 year following the issuance of a regulation based upon this proposal shall comply with the regulation, except for any provisions that may be stayed by the filing of proper objections.

The Commissioner has considered the environmental effects of the issuance or amendment of food standards and has concluded in § 25.1(d)(4) (21 CFR 25.1(d)(4)) that food standards are not major agency actions significantly affecting the quality of the human environment. Therefore, an environmental impact statement is not required for this proposal.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 401,

701(e), 52 Stat. 1046 as amended, 70 Stat. 919 as amended (21 U.S.C. 341, 371(e))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Parts 131 and 133 as follows:

1. Part 131 is amended by adding new § 131.300 as follows:

§ 131.300 Milk and cream substitutes.

(a) *Description.* A milk or cream substitute is a food made in semblance of a standardized food as otherwise defined in this part in which safe and suitable nonmilk ingredients replace all or part of the nutritive milk components of the milk or cream foods simulated, whether or not the food is fluid, concentrated, dried, or in frozen form. The milk or cream substitute shall be pasteurized, ultrapasteurized, or sealed in a container and so processed by heat, either before or after sealing, as to prevent spoilage. The milk or cream substitute shall possess similar physical and organoleptic properties to the food simulated and the fat and solids-not-fat content of the milk or cream substitute shall meet the milkfat and milk solids-not-fat requirements contained in the standard of identity of the counterpart milk or cream food. In addition, the milk or cream substitute shall meet the requirements in paragraph (b) of this section.

(b) *Nutritional equivalency.* A milk or cream substitute that is nutritionally inferior to the milk or cream food it simulates shall be labeled as an "imitation" milk or cream substitute, as required by § 101.3(e) of this chapter. For purposes of § 101.3(e)(2) of this chapter, a milk or cream substitute shall be considered nutritionally equivalent to the food being simulated if it meets all of the following applicable requirements:

(1) *Nutrient profiles for substitutes simulating milk and cream foods.* (i) Nutrient profile for substitutes simulating whole milk foods:

[Percent by weight]

Foods:	*Minimum protein content*
Milk	3.3
Evaporated milk	6.8
Dry whole milk	26.0
Plain whole milk yogurt	3.5
Other nutrients:	*Amount per gram of protein*
Calcium, milligrams	36.0
Magnesium, milligrams	3.5
Phosphorus, milligrams	29.0
Potassium, milligrams	46.0
Zinc, milligrams	.13
Vitamin C, milligrams	.26
Thiamine, milligrams	.01
Riboflavin, milligrams	.04
Pantothenic acid, milligrams	.10
Vitamin B_6, milligrams	.01
Folacin, micrograms	1.6
Vitamin B_{12}, micrograms	.09
Vitamin A, international units	36.0

(ii) Nutrient profile for substitutes simulating lowfat milk foods:

[Percent by weight]

Foods:	*Minimum protein content*
Lowfat milk, 0.5 to 2 percent fat	3.3
Plain lowfat yogurt, 0.5 to 2 percent fat	3.5
Lowfat dry milk, 5.0 to 19.9 percent fat	29.0
Other nutrients:	*Amount per gram of protein*
Calcium, milligrams	36.0
Magnesium, milligrams	3.7
Phosphorus, milligrams	29.0
Potassium, milligrams	47.0
Zinc, milligrams	.13
Vitamin C, milligrams	.26
Thiamine, milligrams	.01
Riboflavin, milligrams	.04
Pantothenic acid, milligrams	.10
Vitamin B_6, milligrams	.01
Folacin, micrograms	1.6
Vitamin B_{12}, micrograms	.11
Vitamin A, international units	[1]18.9

[1]The value, 18.9 international units, for vitamin A is applicable to substitutes for lowfat yogurt and other nonstandardized lowfat milk products except lowfat dry milk. A lowfat dry milk substitute shall contain added vitamins A and D such that, when prepared according to label directions, each quart contains 400 international units of vitamin D and not less than 2,000 international units of vitamin A.

(iii) Nutrient profile for substitutes simulating skim milk foods:

[Percent by weight]

Foods:	*Minimum protein content*
Skim milk	3.4
Evaporated skimmed milk	7.6
Nonfat dry milk	35.0
Other nutrients:	*Amount per gram of protein*
Calcium, milligrams	36.0
Magnesium, milligrams	3.3
Phosphorus, milligrams	28.0
Potassium, milligrams	48.0
Zinc, milligrams	.12
Vitamin C, milligrams	.20
Thiamine, milligrams	.01
Riboflavin, milligrams	.04
Pantothenic acid, milligrams	.10
Vitamin B_6, milligrams	.01
Folacin, micrograms	1.3
Vitamin B_{12}, micrograms	.09
Vitamin A, international units	[1]
Vitamin D, international units	[1]

[1]As required by the standard of identity for the food simulated. An evaporated skimmed milk substitute shall contain added vitamins A and D such that each fluid ounce of the food contains 25 international units of vitamin D and not less than 125 international units of vitamin A.

(iv) Nutrient profile for substitutes simulating cultured buttermilk:

	Percent by weight
Minimum protein content	3.3
Other nutrients:	*Amount per gram of protein*
Calcium, milligrams	35.0
Magnesium, milligrams	3.3
Phosphorus, milligrams	27.0
Potassium, milligrams	46.0
Zinc, milligrams	.13
Ascorbic acid, milligrams	.30
Thiamine, milligrams	.01
Riboflavin, milligrams	.05
Pantothenic acid, milligrams	.08
Vitamin B_6, milligrams	.01
Vitamin B_{12} micrograms	.07

(v) Nutrient profile for substitutes simulating sweetened condensed milk:

	Percent by weight
Minimum protein content	7.9
Other nutrients:	*Amount per gram of protein*
Calcium, milligrams	36.0
Magnesium, milligrams	3.2
Phosphorus, milligrams	32.0
Potassium, milligrams	47.0
Zinc, milligrams	.12
Thiamine, milligrams	.01
Riboflavin, milligrams	.05
Pantothenic acid, milligrams	.10
Vitamin B_{12} micrograms	.06
Vitamin A, international units	41.0

(vi) Nutrient profile for substitutes simulating cream:

	Amount per gram of fat
Nutrient: Vitamin A, international units	37.7

(2) The zinc requirement is doubled if the protein component of the milk substitute is obtained primarily from vegetable protein products.

(3) The protein efficiency ratio (PER) of the protein component of the milk substitute shall be at least 108 percent of that of casein.

(4) Substitutes for milk foods, in addition to the vitamin requirements established in paragraph (b)(1) of this section, are also required to contain an additional amount of vitamin A or vitamin D equivalent to that of the food simulated when the food simulated is required by an applicable standard of identity to contain these added vitamins in a prescribed amount. Further, if the standard of identity for the food simulated provides for the optional addition of vitamins A and/or D, then the food substitute simulating that food will contain vitamins A and/or D in an amount equivalent to that prescribed in the applicable standard of identity for the food simulated.

(5) Compliance with the requirements for other nutrients in this paragraph will be deemed to have been met if reasonable overages of vitamins and minerals, within limits of good manufacturing practice, are present to insure that the required levels are maintained throughout the life of the food under customary conditions of distribution and storage.

(c) *Methods of analysis.* The following referenced methods of analysis are from "Official Methods of Analysis of the Association of Official Analytical Chemists," 12th Ed., 1975.[1]

(1) *Fat content.* "Fat—Official Final Action," sections 16.052, 16.114, 16.129, 16.156, and 16.157, as appropriate.

(2) *Moisture content.* "Moisture—Official Final Action," section 16.149.

(3) *Solids-not-fat content.* Calculated by subtracting the fat content from

[1]Copies may be obtained from the Association of Official Analytical Chemists, P.O. Box 540, Benjamin Franklin Station, Washington, D.C. 20044.

the total solids content as determined by the method "Total Solids, Method I—Official Final Action," section 16.032.

(4) *Protein content.* "Nitrogen—Official Final Action," section 16.036.

(5) *Protein efficiency ratio.* "Biological Evaluation of Protein Quality—Official Final Action," sections 43.183 through 43.187.

(6) Analyses for other nutrients shall be carried out in accordance with Association of Official Analytical Chemists (AOAC) methods when available or by other recognized methods.

(d) *Nomenclature.* (1) The name of the food that substitutes for, or that is made in semblance of, a standardized milk or cream food and that complies with the definition for such food as set forth in paragraph (a) of the section shall be "——— substitute," the blank being filled in with the name of the food simulated, e.g., "lowfat milk substitute." The name of the food shall be accompanied by a descriptive phrase identifying the nonmilk ingredients used to replace the milk components.

(2) When required by the standard of identity for the food simulated, the name of the milk or cream substitute shall be accompanied by a declaration of the amount of fat, e.g., "——— percent fat," or "——— percent vegetable and milkfat," as appropriate, the blank being filled in with the whole number closest to the actual fat content of the food.

(3) If vitamins A and/or D are added to a milk food substitute at levels above those required by paragraph (b)(1) of this section, the name of the milk food substitute shall be accompanied by a phrase such as "vitamin A" or "vitamin A added," or "vitamin D" or "vitamin D added," or "vitamins A and D," or "vitamins A and D added," as appropriate. The word "vitamin" may be abbreviated "vit." Vitamin A and/or D requirements indicated in paragraph (b)(1) of this section by a footnote also cause the name of that food to be accompanied by one of the applicable phrases in this subparagraph.

(4) The name of the food shall appear on the principal display panel of the label in type of uniform size, style, and color. The declaration of the amount of fat, when applicable, and the descrtiptive phrase shall be in letters not less than one-half the height of the largest type appearing in the name of the food.

(5) The name of the food shall be accompanied by a declaration indicating the presence of any characterizing flavoring, in the manner specified in § 101.22 of this chapter.

(6) If the food has been ultra-pasteurized, the word "ultrapasteurized" shall accompany the name of the food wherever it appears on the principal display panel or panels of the label in letters not less than one-half the height of the largest type appearing in such name.

(e) *Label declaration.* Each of the ingredients used shall be declared on the label as required by the applicable sections of part 101 of this chapter.

2. Part 133 is amended by adding a new § 133.300 as follows:

§ 133.300 Cheese substitutes.

(a) *Description.* A cheese substitute is a food made in semblance of a standardized cheese variety, process cheese, cheese product, or other standardized foods made of cheese in which safe and suitable nonmilk ingredients replace all or part of the nutritive milk components normally found in the food being simulated. The cheese substitute shall possess similar physical and organoleptic properties and may meet the fat and moisture requirements set forth in the standard of identity for the food being simulated where such requirements exist. In addition, the cheese substitute shall meet the requirements set out in paragraph (b) of this section.

(b) *Nutritional equivalency.* A cheese substitute that is nutritionally inferior to the cheese or cheese product being simulated shall be labeled "imitation" as required by § 101.3 of this chapter. For purposes of this chapter, a cheese substitute is considered to be nutritionally equivalent to the food being simulated if it meets all of the following applicable requirements.

(1) *Nutrient profile for substitutes simulating cheese and cheese products.* (i) Nutrient profile for substitutes simulating cream cheese and neufchatel cheese:

	Percent by weight
Minimum protein content	9

Other nutrients:	*Amount per gram of protein*
Calcium, milligrams	9.0
Riboflavin, milligrams	0.02
Vitamin A, international units	146.0

(ii) Nutrient profile for substitutes simulating cottage cheese, lowfat cottage cheese, and dry curd cottage cheese:

	Percent by weight
Minimum protein content	14

Other nutrients:	*Amount per gram of protein*
Calcium, milligrams	4.0
Potassium, milligrams	6.0
Zinc, milligrams	.03
Riboflavin, milligrams	.01
Pantothenic Acid, milligrams	.02
Vitamin B_6, milligrams	.01
Folacin, micrograms	1.0
Vitamin B_{12}, micrograms	.05

(iii) Nutrient profile for substitutes simulating other natural cheeses such as cheddar, swiss, mozzarella, blue, and edam:

	Percent by weight
Minimum protein content	24

Other nutrients:	*Amount per gram of protein*
Calcium, milligrams	28.0
Phosphorus, milligrams	19.0
Zinc, milligrams	.10
Riboflavin, milligrams	.02
Vitamin B_{12}, micrograms	.05
Vitamin A, international units	39.0

(iv) Nutrient profile for substitutes simulating process cheese and cheese products:

[Percent by weight]

Foods:	*Minimum protein content*
Process cheese substitute	23
Cheese product substitute	16

Other nutrients:	*Amount per gram of protein*
Calcium, milligrams	30.0
Phosphorus, milligrams	30.0
Potassium, milligrams	14.0
Zinc, milligrams	.15
Riboflavin, milligrams	.02
Pantothenic acid, milligrams	.03
Vitamin B_{12}, micrograms	.05
Vitamin A, international units	44.0

(2) The zinc requirement is doubled if the protein component of the cheese substitute is obtained primarily from vegetable protein products.

(3) The protein efficiency ratio (PER) of the protein component of the cheese or cheese product substitute shall be at least 100 percent of that of casein.

(4) Compliance with the requirements for other nutrients in this paragraph will be deemed to have been met if reasonable overages of vitamins and minerals, within limits of good manufacturing practice, are present to insure that the required levels are maintained throughout the life of the food under customary conditions of distribution and storage.

(c) *Method of analysis.* The following reference methods of analysis are from "Official Methods of Analysis of the Association of Official Analytical Chemists," 12th Ed., 1975.[1]

(1) *Fat content.* "Fat—Official Final Action," section 16.230.

(2) *Moisture content.* "Moisture—Official Final Action," sections 16.217, 16.218, or 16.219 through 16.222, as appropriate.

(3) *Protein content.* "Nitrogen—Official Final Action," section 16.226.

(4) *Protein efficiency ratio.* "Biological Evaluation of Protein Quality—Official final Action," sections 43.183 through 43.187.

(5) Analyses for other nutrients shall be carried out in accordance with Association of Official Analytical Chemists (AOAC) methods when

available or by other recognized methods.

(d) *Nomenclature.* (1) The name of the food that substitutes for or that is made in semblance of a standardized cheese variety, process cheese, cheese product, or other standardized food made of cheese and that complies with the definition for such food set forth in paragraph (a) of this section shall be "——— substitute," the blank being filled in with the name of the food simulated as provided for in the standard of identity for that food, e.g., "cheddar cheese substitute," or "process swiss cheese substitute." The name of the food shall be accompanied by a descriptive phrase identifying the nonmilk ingredients, if used in the food, to replace the milk protein. The name of the food shall also be accompanied by a declaration of the amount and type(s) of fat in the cheese substitute, e.g., "——— percent vegetable fat and milkfat," the blank being filled in with the whole number closest to the actual fat content of the food.

(2) In cases where the fat and moisture content requirements of the standardized food being simulated are optionally variable, e.g., in process cheese products, or when the fat and moisture contents of the cheese substitute vary from that the standardized food simulated, and the food complies with the definition for such food as required in paragraph (a) of this section, the name of the food shall be "——— product substitute," the blank being filled in with the name of the food simulated, e.g., "process cheddar cheese product substitute." The name of the food shall be accompanied by a descriptive phrase identifying any nonmilk ingredients used in the food to replace the milk protein. The name of the food shall also be accompanied by a declaration of the amount and type(s) of fat in the cheese product substitute, e.g., "——— percent vegetable fat and milkfat," the blank being filled in with the whole number closest to the actual fat content of the food.

(3) The use of the term "pasteurized" in the name of process cheese substitutes and the terms "pasteurized" and "process" in the name of cheese product substitutes is optional.

(4) The name of the food shall appear on the principal display panel of the label in type of uniform size, style, and color. The declaration of fat content, when required, and the descriptive phrase shall be in letters not less than one-half the height of the largest type appearing in the name of the food.

(5) The name of the food shall be accompanied by a declaration indicating the presence of any characterizing flavoring, including smoke and substances prepared by condensing or precipitating wood smoke, and any characterizing spice in the manner specified in § 101.22 of this chapter.

(6) The word "cheese" or any varietal name of a cheese or food made of cheese shall not appear on the label except as permitted by this section. Words or phrases suggesting possible uses of the cheese substitute, such as "for pizza" or "for salads," or descriptive phrases such as "sliced" or "sharp," may appear on the label, but shall be separate from the name of the food.

(e) *Label declaration.* The common or usual name of each of the ingredients used shall be declared on the label as required by the applicable sections of Part 101 of this chapter.

Interested persons may, on or before November 27, 1978, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Room 4-65, 5600 Fishers Lane, Rockville, Md. 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the hearing clerk docket numbers found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

In accordance with Executive Order 12044, the economic effects of this proposal have been carefully analyzed, and it has been determined that the proposed rulemaking does not involve major economic consequences as defined by that order. A copy of the regulatory analysis assessment supporting this determination is on file with the Hearing Clerk, Food and Drug Administration.

Dated: September 8, 1978.

DONALD KENNEDY,
Commissioner of Food and Drugs.

NOTE.—Incorporation by reference approved by the Director of the Office of the Federal Register on March 11, 1976, and is on file in the Federal Register Library.

[FR Doc. 78-25816 Filed 9-18-78; 8:45 am]

[4110-03]

[21 CFR Part 133]

[Docket No. 77P-0071]

SKIM MILK CHEESE FOR MANUFACTURING

Proposal To Amend Identity Standards; Reopening of Comment Period

AGENCY: Food and Drug Administration.

ACTION: Reopening of comment period.

SUMMARY: The Food and Drug Administration (FDA) is reopening the comment period on a proposed rule that would amend the standards of identity for skim milk cheese for manufacturing. This action is based on requests from industry. The reopened comment period will run concurrently with the comment periods for two proposed rules published elsewhere in this issue of the FEDERAL REGISTER: The proposed rule to establish standards of identity for milk, cream, and cheese substitutes and the proposed rule to revise the standards of identity for nine natural cheeses based on the international standards for these foods.

DATE: New deadline for comments November 27, 1978.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Room 4-65, 5600 Fishers Lane, Rockville, Md. 20857.

FOR FURTHER INFORMATION CONTACT:

Eugene T. McGarrahan, Bureau of Foods (HFF-415), Food and Drug Administration, Department of Health, Education, and Welfare, 200 C Street SW., Washington, D.C. 20204, 202-245-1155.

SUPPLEMENTARY INFORMATION: In the FEDERAL REGISTER of October 4, 1977 (42 FR 53979), the Commissioner of Food and Drugs proposed to amend the identity standard for skim milk cheese for manufacturing. Comments were to be filed on the proposal by December 5, 1977.

Subsequently, the Commissioner received several requests from industry for extension of the comment period on the proposal. In view of two other related proposals the agency planned to issue, the Commissioner decided not to extend the comment period at that time but rather, to reopen the comment period on publication of the new proposals. These new proposals which would: (1) establish standards of identity for milk, cream, and cheese substitutes (docket No. 75P-0121), and (2) revise the standards of identity for nine natural cheeses based on a review of the recommended international standards for these foods (docket No. 77N-0331), are published elsewhere in this issue of the FEDERAL REGISTER.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 401, 701(e), 52 Stat. 1046 as amended, 70 Stat. 919 as amended (21 U.S.C. 341, 371(e))), and under authority delegated to the Commissioner (21 CFR 5.1), the comment period on the proposal for skim milk cheese for manufacturing is hereby reopened and shall run concurrently with the comment periods established for the proposals for milk, cream, and cheese substitutes and for the nine natural cheeses.

Interested persons may, on or before November 27, 1978, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Room 4-65, 5600 Fishers Lane, Rockville, Md. 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the hearing clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 8, 1978.

JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-25817 Filed 9-18-78; 8:45 am]

[4110-03]

[21 CFR Part 133]

[Docket No. 77P-0070]

PASTEURIZED PROCESS CHEESE AND CHEESE PRODUCTS

Proposed Revision of Definition and Standards of Identity; Reopening of Comment Period

AGENCY: Food and Drug Administration.

ACTION: Reopening of comment period.

SUMMARY: The Food and Drug Administration (FDA) is reopening the comment period on a proposed rule that would revise the standards of identity for pasteurized process cheese and pasteurized process cheese products. This action is based on requests from industry. The reopened comment period will run concurrently with the comment periods for two proposed rules published elsewhere in this issue of the FEDERAL REGISTER: The proposed rule to establish standards of identity for milk, cream, and cheese substitutes and the proposed rule to revise the standards of identity for nine natural cheeses based on the international standards for these foods.

DATE: New deadline for comments November 27, 1978.

ADDRESS: Written comments to Hearing Clerk (HFA-305), Food and Drug Administration, Room 4-65, 5600 Fishers Lane, Rockville, Md. 20857.

FOR FURTHER INFORMATION CONTACT:

Eugene T. McGarrahan, Bureau of Foods (HFF-415), Food and Drug Administration, Department of Health, Education, and Welfare, 200 C Street SW., Washington, D.C. 20204, 202-245-1155.

SUPPLEMENTARY INFORMATION: In the FEDERAL REGISTER of October 4, 1977 (42 FR 53970), the Commissioner of Food and Drugs proposed revision of the standards of identity for pasteurized process cheese and other pasteurized process cheese products. Comments were to be filed on the proposal by January 3, 1978.

Subsequently, the Commissioner received several requests from industry for extension of the comment periods on the proposal. In view of two other related proposals the agency planned to issue, the Commissioner decided not to extend the comment period at that time but rather, to reopen the comment period on publication of the new proposals. These new proposals which would: (1) establish standards of identity for milk, cream, and cheese substitutes (docket No. 75P-0121), and (2) revise the standards of identity for nine natural cheeses based on a review of the recommended international standards for these foods (docket No. 77N-0331), are published elsewhere in this issue of the FEDERAL REGISTER.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 401, 701(e), 52 Stat. 1046 as amended, 70 Stat. 919 as amended (21 U.S.C. 341, 371(e))) and under authority delegated to the Commissioner (21 CFR 5.1), the comment period on the proposal for pasteurized process cheese and other pasteurized process cheese products is hereby reopened and shall run concurrently with the comment periods established for the proposals for milk, cream, and cheese substitutes and for the nine natural cheeses.

Interested persons may, on or before November 27, 1978, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Room 4-65, 5600 Fishers Lane, Rockville, Md. 20857, written comments regarding this proposal.

Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the hearing clerk docket number found in brackets in the hearing of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 8, 1978.

JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-25820 Filed 9-18-78; 8:45 am]

[4110-03]

[21 CFR Part 133]

[Docket No. 77N-0331]

CHEESES AND RELATED CHEESE PRODUCTS

Proposal Based on International Standards

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: This proposal would revise and update the standards of identity for nine cheese and appropriate cross-referenced standards. In addition, amendments to the nine cheese standards are proposed to bring them into closer conformance with international standards recommended by the Codex Alimentarius Commission. Any regulation issued on the basis of this proposal will reflect the Commissioner's consideration of relevant information presented at the food labeling hearings announced in the FEDERAL REGISTER on June 9, 1978.

DATES: Comments by November 27, 1978. Proposed compliance for products initially introduced into interstate commerce: One year after the date of issuance of a regulation.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Room 4-65, 5600 Fishers Lane, Rockville, Md. 20857.

FOR FURTHER INFORMATION CONTACT:

Eugene T. McGarrahan, Bureau of Foods (HFF-415), Food and Drug Administration, Department of Health, Education, and Welfare, 200 C Street SW., Washington, D.C. 20204, 202-245-1155.

SUPPLEMENTARY INFORMATION: The Food and Drug Administration (FDA) is proposing to revise the standards of identity for blue cheese, cheddar cheese, edam cheese, gouda cheese, gruyere cheese, limburger cheese, provolone cheese, samsoe cheese, swiss cheese, and the cross-referenced cheeses—cheddar cheese for manufacturing, low sodium cheddar cheese, and swiss cheese for manufacturing. The purpose of these revisions is to: (1) Provide for full ingredient declaration; (2) relax recipe requirements to permit use of safe and suitable ingredients that do not change the basic identity of the food or adversely affect the physical or chemical characteristics; and (3) amend compositional requirements to be consistent with the "recommended international standards" (hereinafter referred to as Codex standards), where it will promote honesty and fair dealing in the consumers' interest.

All FDA regulations concerning human food were reorganized under

Subchapter B—Food for Human Consumption, published in the FEDERAL REGISTER of March 15, 1977 (42 FR 14302). For the convenience of the reader, the following table lists the former designation of the sections in recodified subchapter B that would be affected by this proposal.

New section:	Old section:
133.3	19.499
133.106	19.565
133.113	19.500
133.114	19.502
133.116	19.503
133.138	19.555
133.142	19.560
133.149	19.543
133.152	19.575
133.181	19.590
133.185	19.544
133.195	19.540
133.196	19.542

The Joint Food and Agriculture Organization/World Health Organization (FAO/WHO) Committee of Government Experts on the Code of Principles Concerning Milk and Milk Products, an auxiliary body of the Codex Alimentarius Committee, has submitted standards of identity for 34 natural cheeses to the United States for consideration of acceptance. The United States has 11 corresponding standards of identity, and the 9 included in this document cover the principal cheeses used in this country. The remaining two (cottage cheese and cream cheese) will not be considered in this document, because they are subject to further revision by Codex.

The Commissioner is taking the opportunity presented by the U.S. obligation to consider Codex standards for adoption to revise and update the standards of indentity for nine cheeses for which there are also Codex standards and to revise appropriate cross-referenced standards. The proposed revision is in keeping with recent vevisions of other standards of indentity to provide consumers with more complete ingredient information and to accommodate changes in the availability of ingredients as well as technological advances. The other 23 Codex standards will be considered for acceptance at a later date.

The Commissioner believes that the proposed changes will promote honesty and fair dealing in the interest of consumers and will facilitate international trade.

REVISION OF EXISTING STANDARDS OF IDENTITY

The Commissioner proposes that the standards of indentity for blue cheese (21 CFR 133.106), cheddar cheese (21 CFR 133.113), edam cheese (21 CFR 133.138), gouda cheese (21 CFR 133.142), gruyere cheese (21 CFR 133.149), limburger cheese (21 CFR 133.152), provolone cheese (21 CFR 133.181), samsoe cheese (21 CFR 133.185), and swiss and emmentaler cheese (21 CFR 133.195) and, by cross-reference, cheddar cheese for manufacturing (21 CFR 133.114), low sodium cheddar cheese (21 CFR 133.116), and swiss cheese for manufacturing (21 CFR 133.196) be revised. The revisions would (1) adopt the use of functional group designations for safe and suitable optional ingredients, where appropriate, and require that all ingredients be declared on the label by their common or usual name in accordance with part 101 (21 CFR part 101); (2) provide for the use of various forms of milk, nonfat milk, and cream; (3) require that a label declaration of fat content accompany the name of the food; and (4) delete the methods of analysis from the individual standards and establish a new § 133.5, titled "Methods of analysis."

The Commissioner is of the opinion that it is unduly restrictive to limit a manufacturer's choices of ingredients by specifically listing each optional ingredient that may be used. He believes that the use of functional group designation of optional ingredients benefits the consumer by allowing a manufacturer to select less expensive or more readily available ingredients that are equally appropriate for a functional purpose. Safety and suitability of ingredients chosen from a functional group are governed by the definition of "safe and suitable" in § 130.3(d) (21 CFR 130.3(d)) in conjunction with appropriate food additive regulations established under parts 170, 171 and 172 (21 CFR parts 170, 171 and 172). The Commissioner believes that the use of safe and suitable functional categories will minimize any future need to amend the standards to provide for additional specific ingredients. Therefore, wherever practicable, he is proposing the use of functional group terminology, established by § 170.3 (21 CFR 170.3), for safe and suitable optional ingredients.

The Commissioner is further proposing that various forms of milk, nonfat milk, and cream be provided for. The existing cheese standards specify that the basic ingredient for cheese manufacture is fluid cow's milk which may have the fat of solids-not-fat levels adjusted by removing milkfat or adding cream, nonfat milk, concentrated skim milk of nonfat dry milk. The Commissioner believes that, technologically, alternate forms of milk, nonfat milk, and cream, i.e., concentrated, dried, and reconstituted forms, can be used to produce the same cheese as produced from fluid cow's milk. Further, he is of the opinion that provision for alternate forms of these milk products would be consistent with the provision in the existing standards for alternate manufacturing procedures that do not adversely affect the physical and chemical properties of the cheese. The Commissioner, therefore, is proposing to allow the use of specific classes of optional dairy ingredients, i.e., "milk," "cream," and "nonfat milk." He is also proposing definitions for the class designations "milk," "cream," and "nonfat milk" in the definitions section, § 133.3.

The Commissioner is aware of consumers' desire to be informed of the ingredients used in the foods they consume. In accordance with the policy set forth in § 101.6 (21 CFR 101.6), the Commissioner proposes to amend the standards of identity for the nine cheeses and the cross-referenced cheeses to require label declaration of optional ingredients in accordance with part 101. All ingredients in these cheeses are optional ingredients, with the exception of salt (except in the cross-referenced cheese, low sodium cheddar (§ 133.116)). While cheese must contain forms of milk, nonfat milk or cream, the manufacturer has the option of choosing, within specific classes of milk products, those forms he prefers to use. Section 403(k) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343(k)) specifically exempts cheese from any label declaration of optional artificial coloring. Salt, a mandatory ingredient in most of the cheeses, also is exempt from the ingredient statement requirement. However, the Commissioner urges manufacturers to declare the presence of these ingredients when used.

The standards of identity for blue cheese (§ 133.106), provolone cheese (§ 133.181), and swiss cheese (§ 133.195) provide for the use of the optional ingredient benzoyl peroxide to bleach milk products. These existing standards require that use of benzoyl peroxide be declared on the label by the statement "Milk bleached with benzoyl peroxide." Under this proposed revision, benzoyl peroxide is an optional ingredient and as such must be declared in the ingredient statement of the cheese. The Commissioner advises that its use maybe declared either as "benzoyl peroxide" or "—— bleached with benzoyl peroxide" with the appropriate name(s) of the milk products filling the blank.

The Commissioner is also proposing that the milkfat content of each cheese be declared, by weight, on the label. In conjunction with this, it is proposed that the minimum milkfat requirements in each of the subject cheese standards of identity be expressed on an "as is" basis, i.e., the percentage by weight of the finished food. Currently minimum milkfat requirements are expressed on a "dry basis" as a percentage of the solid matter in the cheese, i.e., excluding the moisture content. The Commissioner is of the opinion that such an

expression of fat content has little or no meaning to the average consumer. Moreover, the actual fat content of a cheese may vary from the minimum, upward. The Commissioner is of the opinion that the phrase "contains —— % fat," based on the weight of the finished food including moisture, with the whole number nearest the actual milkfat content of the cheese filling the blank and accompanying the name of the food, would more fully inform the consumer about the food.

Regarding other changes in the existing standards, the Commissioner is proposing to delete the definition of "safe and suitable" from the "Definitions" section (§ 133.3) and add definitions for "pasteurized" and "ultrapasteurized," in addition to the definitions for classes of dairy ingredients named above. "Safe and suitable" is already defined in § 130.3(d). Definition of the other terms he proposes to include in § 133.3 would eliminate the needless repetition of each term in each standard of identity. For the same reason, the Commissioner proposes that a new § 133.5, titled "methods of analysis" be established. This section will include the methods of analysis for milkfat, moisture, and phosphatase contents referred to in each of the standards. The other standards in part 133 will be revised to refer to §§ 133.3 and 133.5 at a later date.

The Commissioner is also proposing that all cheese standards of identity included in this proposal provide for a miximum allowable phenol equivalent value. The existing standards of identity for blue cheese (§ 133.106), gruyere cheese (§ 133.149), limburger cheese (§ 133.152), samsoe cheese (§ 133.185), and swiss cheese (§ 133.195) do not include a specific maximum allowable phenol equivalent value. The standards for the other four cheeses do include a specific value. The phenol equivalent value indicates whether proper pasturization procedures were followed when a cheese purports to be made from pasteurized milk products. A phenol equivalent value above the maximum allowed for a specific cheese that claims to be made from pasteurized milk products might indicate that improper pasteurization times and/or temperatures were used. The phenol equivalent value is determined by the "Fesidual Phosphatase" test described in section 16.245 of the 12th edition of "Official Methods of Analysis of the Association of Official Analytical Chemists" (AOAC). This entire test procedure is now included in the standard of identity for cheddar cheese (§ 133.113). When the new § 133.5, Methods of analysis, is established, the procedure will be removed from the cheddar cheese standard and replaced with a reference to the AOAC method in § 133.5. All cheese standards included in this proposal that now refer to the cheddar cheese standard for the method of determining the phenol equivalent value will be amended to refer to the new § 133.5. All the cheese standards not covered by this proposal will be similarly amended in the future.

The AOAC procedure also includes a table of cheese varieties and types and corresponding phenol equivalent values. These values were established from data obtained after the hearings to establish standards of identity for cheeses and were first published in the 6th edition of "Official Methods of Analysis of the Association of Official Agricultural Chemists" in 1950. From 1950 to 1975 the values were considered experimental by the AOAC, and they were constantly reviewed and updated. In the 12th edition of the AOAC (1975) the term "experimental" was dropped from the values, indicating that these values are recognized as valid. Therefore, the Commissioner is proposing that the phenol equivalent values from the AOAC be accepted for those five cheeses for which the standards that do not now include maximum allowable phenol equivalent values and to retain the values in the standards that do contain them since these values already correspond to the AOAC values.

To ensure that cheeses made from unpasteurized milk products are cured for the length of time specified by each standard of identity, the Commissioner points out that, in accordance with § 101.100(f) (21 CFR 101.100(f)), uncured bulk cheese must be clearly marked with the date the curing process begins.

The Commissioner is further proposing that the provision for hydrogen peroxide/catalase treatment of milk be eliminated from the standards of identity for cheddar cheese (§ 133.113), swiss cheese (§ 133.195), and the cross-referenced cheeses—cheddar cheese for manufacturing (§ 133.114), low sodium cheddar cheese (§ 133.116), and swiss cheese for manufacturing (§ 133.196). He is not aware that this method is in common use and particularly asks for comment on this point.

The standard of identity for provolone cheese (§ 133.181) states that provolone cheese may be smoked, or it may have added to it a clear aqueous solution prepared by condensing or precipitating wood smoke in water. If the food is not smoked, the standard requires that the name of the food include the words "not smoked." If a clear aqueous solution of wood smoke is added, the words "with added smoke flavoring" must immediately follow the name.

The Commissioner is retaining the provision for optional smoking, but is deleting the provision for the addition of smoke flavor since the smoke-flavored cheese would be subject to the requirements of § 133.193 Spiced, flavored standardized cheeses (21 CFR 133.193). Further, he is proposing to delete the words "not smoked" when the food is not smoked and instead is proposing that, if the food is smoked, the work "smoked" shall accompany the name of the food.

Since the name "pasta filata" more correctly refers to a class of cheeses than to a specific variety, the Commissioner is proposing to delete the alternative name "pasta filata" from the standard of identity for provolone cheese (§ 133.181).

Certain standards of identity subject to this proposal do not provide for specific dimensions, weights, or shapes of the cheese, or for coatings that may be applied to the surface before curing. The standards for blue cheese, edam cheese, gouda cheese, and provolone cheese contain provisions for coatings, shapes, or both, while the standard for samsoe cheese provides for specific shape, weight, and dimensions. Traditionally, such cheeses have been produced in distinctive shapes or sizes, and/or have been covered with paraffin of one color or another. The Commissioner recognizes that some consumers may identify the type of cheese by its dimensions, weight, shape, or coating color, but he believes that the name and ingredient labeling requirements of the standards assure the consumer of being adequately informed of the variety of cheese. Therefore, the Commissioner is proposing to remove provisions for coatings and/or cheese shapes from the standards of identity for blue cheese, edam cheese, and gouda cheese; the provisions for specific shapes from the standard of identity for provolone cheese; and the provisions for shape, weight, and dimensions form the standard of identity for samsoe cheese. These changes will allow the use of new manufacturing and packaging techniques as they are developed.

The existing standards of identity for gruyere cheese and swiss cheese provide for the optional use of propionic acid-producing bacterial cultures. The Codex standards for emmentaler cheese (C-9) and gruyere cheese (C-10) require the addition of propionic acid-producing bacterial cultures.

The Commissioner is of the opinion that this type of culture is essential for proper eye-formation characteristic of these two cheese varieties. He, therefore, proposes that propionic acid-producing bacterial cultures, in addition to lactic acid-producing bacterial cultures, be required in the manufacture of gruyere cheese and swiss cheese.

In the cross-referenced standard for low sodium cheddar cheese, the Commissioner is proposing to delete paragraph (b), which prohibits the use of sodium sorbate. He considers this prohibition to be unnecessary since the low sodium cheddar cheese standard contains a maximum sodium limit.

CODEX ALIMENTARIUS RECOMMENDED INTERNATIONAL STANDARDS

The United States, as a member nation of FAO/WHO, is under treaty obligation to consider acceptance of all Codex standards. The rules of procedure of the Codex Alimentarius Commission permit acceptance of a recommended standard in one of three ways: Full acceptance; target acceptance; or acceptance with specified deviations. A participating country which concludes that it cannot accept the standard in full is requested to indicate the ways in which its requirements differ from the recommended international standard. Member nations of the Codex Alimentarius Commission are requested to notify the Technical Secretary, Committee on the Code of Principles Concerning Milk and Milk Products, Animal Production and Health Division, FAO, Rome, Italy, of their decision. When a sufficient number of governments accept these standards, the Secretariat of the Committee will notify the Codex Alimentarius Commission and request the publication of the accepted standards as worldwide standards by the Commission.

The United States is now considering acceptance of Codex standards of identity for nine natural cheeses. The nine Codex standards and corresponding U.S. standards are as follows:

	Codex	United States
Blue-veined	C-32	133.106
Cheddar	C-1	133.113
Edam	C-4	133.138
Gouda	C-5	133.142
Gruyere	C-10	133.149
Limburger	C-12	133.152
Provolone	C-15	133.181
Samsoe	C-7	133.185
Swiss or Emmentaler	C-9	133.195

Based on the treaty obligation and the policy set forth in § 130.6 (21 CFR 130.6), the Commissioner proposes to amend the compositional requirements of the standards of identity for these nine cheeses, wherever practicable, to effect consistency with the Codex standards.

The Codex standards include certain labeling requirements that are not considered a part of food standards of identity under section 401 of the Federal Food, Drug, and Cosmetic Act. Such requirements are authorized by other sections of the act, the Fair Packaging and Labeling Act, and regulations promulgated thereunder in part 101 (21 CFR Part 101) and are applicable to all products entered into interstate commerce is the United States.

The Codex standards also reference specific methods of sampling in FAO/WHO Standard B-1, "Sampling Methods for Milk and Milk Products," paragraphs 2 and 7 (CAC/M1-1973).[1] Such sampling methods are not specifically designated in the U.S. standards of identity for cheeses and cheese products. However, these FAO/WHO sampling methods have been published in the "Official Methods of Analysis of the Association of Official Analytical Chemists," 12th ed., 1975, the source of the referenced methods of analysis for cheese and cheese products contained in the U.S. standards of identity.

Although the individual Codex standards are similar to corresponding U.S. standards, including proposed revisions, significant variations do exist in several instances which merit discussion. The texts of the Codex Recommended International Standards under consideration follow:

Appendix V-3.

STANDARD NO. C-32, STEP 7

Submitted to Governments for Acceptance

INTERNATIONAL STANDARD FOR CERTAIN BLUE-VEINED CHEESES

1. *Scope.* This standard applies to the following varieties of blue-veined cheese: Danablu, Edelpilzkase, Adelost, Blue Cheese.

2. *Depositing countries:* Denmark, Federal Republic of Germany, Sweden, United States of America.

3. *Raw Materials.*

3.1 Kind of milk: Cow's milk.

3.2 Authorized additions:

3.2.1 Necessary additions: Cultures of harmless lactic acid producing bacteria (starter); rennet or other suitable coagulating enzymes; sodium chloride; and cultures of *penicillium roqueforti.*

3.2.2 Optional additions: Water; calcium chloride, maximum 200 mg/kg of the milk used; *beta*-carotene maximum 600 mg/kg of cheese; chlorophyll copper complex; riboflavin (lactoflavin); and harmless preparations of enzymes capable of aiding in the curing or flavor development (weight of solids of such substance added, not to exceed 0.1 percent of weight of milk used).

4. *Principal characteristics of the cheese ready for consumption.*

4.1 Type.

4.1.1 Consistency: Semi-hard to soft.

4.1.2 Short description: Blue-veined semihard cheese mainly ripened by internal mold growth.

4.2 Shapes: (a) Flat cylindrical; (b) flat square; and (c) flat rectangular.

4.3 Dimensions and weights.

4.3.1 Dimensions: Height: approximately 8 to 15 cm.

4.3.2 Weights: 2 to 6 kg.

4.3.2.1 Weights of "Danablu": Flat cylindrical: 2.75 to 3.25 kg; flat square and flat rectangular: approximately 4 kg.

4.4 Rind.

4.4.1 Consistency: No actual rind, but a semihard surface.

4.4.2 Appearance: Greasy to dry.

4.4.3 Color: Whitish.

4.5 Body.

4.5.1 Texture: Suitable for cutting and spreading.

4.5.2 Color: White to yellowish with blue-green veins of mold.

4.6 Holes.

4.6.1 Distribution: Scarce.

4.6.2 Shape: Irregular.

4.6.3 Size: Various.

4.6.4 Appearance: With blue-green molds.

4.7/4.8 Minimum fat content in dry matter and maximum moisture content:

[Percent]

	A	B	C
Minimum fat in dry matter	50	60	45
Maximum moisture content	48	48	55
Minimum dry matter content	52	52	45

The minimum fat content in dry matter and maximum moisture content for Danablu are restricted to those given under A and B.

4.9 Other principal characteristics: Cheese has distinct piquant flavor resulting from fat breakdown. Not to be sold to the consumer at less than 6 weeks of age.

METHOD OF MANUFACTURE

5.1 Method of coagulation: Rennet or other suitable coagulating enzymes; addition of a lactic acid starter.

5.2 Heat treatment: None, or slightly heated after cutting, ladled out in bags or molds.

5.3 Fermentation procedure: Lactic acid and mold fermentation.

5.4 Maturation procedure: Pierced with needles to develop growth of molds; stored humid at a temperature from 2° to 12° C; some surface mold.

5.5 Other principal characteristics: None.

SAMPLING AND ANALYSIS

6.1 Sampling: According to FAO/WHO Standard B.1, "Sampling Methods for Milk and Milk Products," clause 7.2(b), "Sampling by means of a trier"; reference is made to clauses 7.2.2.3 and 7.2.2.5.

6.2 Determination of fat content: According to FAO/WHO Standard B.3, "Determination of the Fat Content of Cheese and Processed Cheese Products."

MARKING AND LABELING

Only cheese conforming with this standard may be designated: (a) "Danablu," or "Edelpilzkase," or "Blue Cheese," or "Adelost," or (b) a combination of the designation "Blue-veined cheese" with the designations given in (a), e.g., "Adelost—blue-veined cheese."

It shall be labeled in conformity with the appropriate sections of Article 4 of FAO/WHO Standard A.6, "General Standard for Cheese" except that Danablu not produced in the country of origin must be marked with the name of the producing country even when sold in the home market.

The cheese mentioned under "B" and "C" in 4.7/4.8 may be designated as mentioned under (a) or (b) above provided that the designation is accompanied by the prefix or

[1] "Code of Principles Concerning Milk and Milk Products, International Standards and Standard Methods of Sampling and Analysis for Milk Products," 7th ed.

suffix corresponding to the fat percentage, e.g., "Edelpilzkase 45%."

The use of food colors shall be indicated on the label.

STANDARD NO. C-1 (1966)

INTERNATIONAL INDIVIDUAL STANDARD FOR CHEDDAR

1. *Designation of cheese:* Cheddar.

2. *Depositing country:* United Kingdom (country of origin).

3. *Raw materials.*

3.1 Kind of milk: Cow's milk.

3.2 Authorized additions.

3.2.1 Necessary additions: Cultures of harmless lactic acid producing bacteria (starter); rennet or other suitable coagulating enzymes; and sodium chloride.

3.2.2 Optional additions: Calcium chloride, maximum 200 mg/kg of the milk used; annattoo* and beta carotene, singly or in combination, maximum 600 mg/kg of cheese; sorbic acid and its sodium and potassium salts, maximum 1,000 mg/kg calculated as sorbic acid; a preparation of safe and suitable enzymes of animal or plant origin capable of aiding in the curing or development of flavor of Cheddar cheese may be added during the procedure, in such quantity that the weight of the solid of such preparation is not more than 1,000 mg/kg of the milk used.

4. *Principal characteristics of the cheese ready for consumption.*

4.1 Type (consistency): Hard pressed.

4.2 Shape: Cylindrical or block (cuboid).

4.3 Dimensions and weights: Various.

4.4 Rind.

4.4.1 Consistency: Hard.

4.4.2 Appearance: Smooth, may be coated with wax or cloth wrapped.

4.4.3 Color: Pale straw through dark straw to orange; rindless blocks may be in airtight, flexible film.

4.5 Body.

4.5.1 Texture: Firm, smooth, and waxy.

4.5.2 Color: Uniform, pale straw through dark straw to orange.

4.6 Holes: Gas holes should be absent; none to few mechanical openings.

4.7 Minimum fat content in dry matter: 48 percent.

4.8 Maximum moisture content: 39 percent. Minimum dry matter content: 61 percent.

4.9 Other principal characteristics: Normally consumed mild from 3 months or mature up to 12 months or more. Flavor typical of the variety, varying in intensity from mild to sharp and typical of ripening controlled by lactic acid producing bacteria.

5. *Method of manufacture.*

5.1 Method of coagulation: Rennet or other suitable coagulating enzymes.

5.2 Heat treatment.

5.2.1 Heat treatment of the milk: Milk for cheesemaking may be raw, heat treated or pasteurized to 161° F (71.7° C) for 15 seconds.

5.2.2 Heat treatment of the coagulum: The curd is subsequently cut and scalded to 100°-106° F (37.5°-40° C) depending on the season.

5.3 Fermentation procedure: 1.0-2.5 percent lactic starter is added to the milk, to give a ripening period of up to 2 hours before rennetting.

5.4 Maturation procedure: After scalding the curd, it is stirred until slight acid development, customarily 0.18 or 0.19 percent expressed as lactic acid, is reached.

The whey is run off and the process of "cheddaring" (which may take place in a separate container) continues, during which the curd is cut into blocks, which are turned and progressively piled. During this process the curd is kept warm and the drainage of whey, together with the development of acidity, results in the curd becoming compressed, smooth, and elastic. When a substantial acidity which may reach 0.90 percent expressed as lactic acid has been reached, the curd is milled.

About 2.0-2.5 percent salt is added to the curd to give 1.5-1.8 percent salt in the cheese.

The curd is then mixed and molded. The cheeses are stored and subsequently graded. They may mature in store for 3-12 months according to temperature of the store and degree of maturity required.

6. *Sampling and analysis.*

6.1 Sampling: According to FAO/WHO Standard B.1, "Sampling Methods for Milk and Milk Products," paragraph 7, "Sampling of Cheese."

6.2 Determination of fat content: According to FAO/WHO Standard B.3, "Determination of the Fat Content of Cheese and Processed Cheese Products."

7. *Marking and labeling.* Only cheese conforming with this standard may be designated "Cheddar." It shall be labeled in conformity with the appropriate sections of Article 4 of FAO/WHO Standard A.6, "General Standard for Cheese."

STANDARD NO. C-4 (1966)

INTERNATIONAL INDIVIDUAL STANDARD FOR EDAM

1. *Designation of cheese:* Edam.[1]

2. *Depositing country:* The Netherlands (country of origin).

3. *Raw materials.*

3.1 Kind of milk: Cow's milk.

3.2 Authorized additions: Cultures of harmless lactic acid producing bacteria (starter); rennet or other suitable coagulating enzymes; sodium chloride; calcium chloride, maximum 200 mg/kg of the milk used; annatto* and beta carotene, singly or in combination maximum 600 mg/kg of cheese; sodium and potassium nitrate, maximum 200 mg/kg of the milk used**; and water.

4. *Principal characteristics of the cheese ready for consumption.*

4.1 Type (consistency): Semihard.

4.2 Shape: (a) Spherical, slightly flattened at the top and the bottom, and (b) flat block with square and/or rectangular side (not being a loaf) and with or without rind.

4.3 Dimensions and weights.

4.3.1 Dimensions: Depend on the shapes (4.2) and weights (4.3.2).

4.3.2 Weights: (a) Spherical (as under 4.2.a) 1.7 to 2.5 kg, and (b) flat block (as under 4.2.b) not less than 10 kg.

4.4 Rind.

4.4.1 Consistency: Hard.

4.4.2 Appearance: Dry, often coated with paraffin, wax, plastic, or a film of vegetable oil; coatings yellow or red.

4.4.3 Color: Yellowish.

4.5 Body.

4.5.1 Texture: Firm, suitable for cutting.

4.5.2 Color: Yellowish.

4.6 Holes.

4.6.1 Distribution: Few, all over the interior of the cheese, distributed regularly as well as irregularly.

4.6.2 Shape: More or less round.

4.6.3 Size: Varying from rice to pea.

4.6.4 Appearance: Not defined.

4.7 Minimum fat content in the dry matter: 40 percent.

4.8 Maximum moisture content: 46 percent. Minimum dry matter content: 54 percent.

4.9 Other principal characteristics: Edam cheese is not normally consumed before it is 5 weeks old.

5. *Baby Edam, loaf Edam,* baby loaf Edam.*

5.1 *Baby Edam.* Small cheeses complying with the requirements for Edam cheese, except those under 4.3.2, 4.8, and 4.9, may be designated as "Baby Edam" provided they comply with the following:

5.1.1 Weights: From 0.840 to 1.100 kg.

5.1.2 Maximum moisture content: 47 percent. Minimum dry matter content: 53 percent.

5.1.3 Other principal characteristics: "Baby Edam" is not normally consumed before it is 3 weeks old.

5.2 *Loaf Edam.* Loaf-shaped cheeses, complying with the requirements for Edam cheese, except those under 4.2 and 4.3.2, may be designated as "Loaf Edam" provided they comply with the following:

5.2.1 Shape: Loaf shaped, length of the long side more than twice that of the shortest.

5.2.2 Weights: 2.0 to 5.0 kg.

5.3 *Baby Loaf Edam.* Loaf-shaped cheeses, complying with the requirements for Edam cheese, except those under 4.2, 4.3.2, 4.8, and 4.9 may be designated as "Baby Loaf Edam" provided they comply with the following:

5.3.1 Shape: Loaf shaped, length of the long side more than twice that of the shortest.

5.3.2 Weights: 0.400 to 1.100 kg.

5.3.3 Maximum moisture content: 47 percent. Minimum dry matter content: 53 percent.

5.3.4 Other principal characteristics: "Baby Loaf Edam" is not ready for consumption before it is 3 weeks old.

6. *Method of manufacture.*

6.1 Method of coagulation: Rennet or other suitable coagulating enzymes.

6.2 Heat treatment: The curd is heated with or without addition of warm water.

6.3 Fermentation procedure: Chiefly lactic acid.

6.4 Maturation procedure: Maturation during storage at a temperature preferably between 10° and 20° C.

6.5 Other principal characteristics: Salted in brine after manufacture.

7. *Sampling and analysis.*

7.1 Sampling: According to FAO/WHO Standard B.1, "Sampling Methods for Milk and Milk Products," clauses 7.2(a) and 7.2.1, "Sampling by cutting." To obtain the required representativity in the case of Edam in loaf form, special attention should be paid—when cutting the slice—to the proportions of rind, heart, etc.

7.2 Preparation of the sample: According to FAC/WHO Standard B.1, "Sampling Methods for Milk and Milk Products," clause 7.4, "Treatment of samples."

7.3 Determination of fat content: According to FAO/WHO Standard B.3, "Determi-

*Temporarily endorsed.

[1] Or such other synonym (e.g., Edamski) derived from the name Edam as will clearly indicate this variety.

*Temporarily endorsed.

**Subject to endorsement.

nation of the Fat Content of Cheese and Processed Cheese Products."

8. *Marking and labelling.* Only cheese conforming with this standard may be designated "Edam." It shall be labelled in conformity with the appropriate sections of Article 4 of FAO/WHO Standard A.6, "General Standard for Cheese." The cheese mentioned under 5.1 may be designated "Edam," *Provided,* That the designation is accompanied by the prefix "Baby." The cheese mentioned under 5.2 may be designated "Edam," *Provided,* That the designation is accompanied by the prefix "Loaf." The cheese mentioned under 5.3 may be designated "Edam," *Provided,* That the designation is accompanied by the prefix "Baby Loaf."

STANDARD NO. C-5 (1966)

INTERNATIONAL INDIVIDUAL STANDARD FOR GOUDA

1. *Designation of cheese:* Gouda.[1]

2. *Depositing country:* The Netherlands (country of origin).

3. *Raw materials.*

3.1 Kind of milk: Cow's milk.

3.2 Authorized additions: Cultures of harmless lactic acid producing bacteria (starter); rennet or other suitable coagulating enzymes; sodium chloride; water; calcium chloride, maximum 200 mg/kg of the milk used; annatto* and beta carotene, singly or in combination; maximum 600 mg/kg of cheese; sodium and potassium nitrate, maximum 200 mg/kg of the milk used.**

4. *Principal characteristics of the cheese ready for consumption.*

4.1 Type (consistency): Semihard.

4.2 Shape: (a) Cylindrical, with convex sides, curving smoothly into the flat top and bottom; the rate height/diameter varying from one-fourth to one-third; (b) flat block with square and/or rectangular sides (not being a loaf) and with or without rind; and (c) loaf, the length of the long side more than twice that of the shortest.

4.3 Dimensions and weights.

4.3.1 Dimensions: (a) Cylindrical, with convex sides (as under 4.2.a): Fixed by prescribed shape (4.2.a) and weights (4.3.2.a); (b) flat block (as under 4.2.b) fixed by prescribed shape (4.2.b) and weight (4.3.2.b); and (c) loaf (as under 4.2.c) fixed by prescribed shape (4.2.c) and weights (4.3.2.c).

4.3.2 Weights: (a) Cylindrical, with convex sides (as under 4.2.a): From 2.5 to 30 kg; (b) flat block (as under 4.2.b): Not less than 10 kg; and (c) loaf (as under 4.2.c): From 2.5 to 5 kg.

4.4 Rind.

4.4.1 Consistency: Hard.

4.4.2 Appearance: Dry or coated with either wax, a suspension of plastic, or a film of vegetable oil.

4.4.3 Color: Yellowish.

4.5 Body.

4.5.1 Texture: Firm, suitable for cutting.

4.5.2 Color: Straw colored.

4.6 Holes.

4.6.1 Distribution: From few to plentiful, all over the interior of the cheese, distributed regularly as well as irregularly.

4.6.2 Shape: More or less round.

4.6.3 Size: Varying from a pin's head to a pea.

4.6.4 Appearance: Not defined.

4.7 Minimum fat content in the dry matter: 48 percent.

4.8 Maximum moisture content: 43 percent. Minimum dry matter content: 57 percent.

4.9 Other principal characteristics: Gouda cheese is not normally consumed before it is 5 weeks old.

5. *Baby Gouda.* Small cheeses complying with the requirements for Gouda cheeses—except those under 4.2, 4.3, 4.8, and 4.9—may be designated as "Baby Gouda," provided they comply with the following:

5.1 Shape: Cylindrical with convex sides, curving smoothly into the flat top and bottom; the rate height/diameter is about one-half.

5.2 Dimensions and weights.

5.2.1 Dimensions: Fixed by prescribed shape (5.1) and weights (5.2.2).

5.2.2 Weights: From 0.180 to 1.500 kg.

5.3 Maximum moisture content: 45 percent. Minimum dry matter content: 55 percent.

5.4 Other principal characteristics: Baby Gouda is not normally consumed before it is 3 weeks old.

6. *Method of manufacture.*

6.1 Method of coagulation: Rennet or other suitable coagulating enzymes.

6.2 Heat treatment: The curd is heated with or without the aid of warm water.

6.3 Fermentation procedure: Chiefly lactic acid.

6.4 Maturation procedure: Maturation during storage at a temperature preferably between 10° and 20° C.

6.5 Other principal characteristics: Salted in brine after manufacture.

7. *Sampling and analysis.*

7.1 Sampling: According to FAO/WHO Standard B.1, "Sampling Methods for Milk and Milk Products," clauses 7.2(a) and 7.2.1, "Sampling by cutting." To obtain the required representativity in the case of Gouda in loaf form and other rectangular blocks, special attention should be paid—when cutting the slice—to the proportions of rind, heart, etc.

7.2 Preparation of the sample: According to FAO/WHO Standard B.1, "Sampling Methods for Milk and Milk Products," clause 7.4, "Treatment of samples."

7.3 Determination of fat content: According to FAO/WHO Standard B.3, "Determination of the Fat Content of Cheese and Processed Cheese Products."

8. *Marking and labeling.*

Only cheese conforming with this standard may be designated "Gouda." It shall be labeled in conformity with the appropriate sections of Article 4 of FAO/WHO Standard A.6, "General Standard for Cheese." The cheese mentioned under 5 may be designated "Gouda," *Provided,* That the designation is accompanied by the prefix "Baby."

STANDARD NO. C-10 (1967)

INTERNATIONAL INDIVIDUAL STANDARD FOR GRUYERE

1. *Designation of cheese:* Gruyere, Greyerzer, Gruviera.

2. *Depositing countries:* Switzerland and France (countries of origin).

3. *Raw materials.*

3.1 Kind of milk: Cow's milk.

3.2 Authorized additions.

3.2.1 Necessary additions: Cultures of harmless lactic acid producing bacteria (starter) and of proprionic acid-producing bacteria; rennet or other suitable coagulating enzymes; sodium chloride; and water.

3.2.2 Optional additions: None.

4. *Principal characteristics of the cheese ready for consumption.*

4.1 Type (consistency): Hard.

4.2 Shape: Round loaf or blocks.

4.3 Dimensions and weight.

4.3.1 Dimensions: Diameter: 40–65 cm, and height: 9–13 cm.

4.3.2 Weight: Minimum 20 kg.

4.4 Rind.

4.4.1 Consistency: Hard.

4.4.2 Appearance: Covered with smear.

4.4.3 Color: Golden yellow to brown.

4.5 Body.

4.5.1 Texture: Sliceable.

4.5.2 Color: Ivory to light yellow.

4.6 Holes.

4.6.1 Distribution: Regular, scarce to plentiful.

4.6.2 Shape: Round.

4.6.3 Diameter: Mainly from 0.5 to 1.0 cm.

4.6.4 Appearance: Mat to brilliant.

4.7 Minimum fat content in the dry matter: 45 percent.

4.8 Maximum moisture content: 38 percent. Minimum dry matter content: 62 percent.

4.9 Other principal characteristics.

4.9.1 Taste and flavor: More or less tangy.

4.9.2 Ready for consumption: The cheese is ready for consumption at a minimum age of 80 days from the day of manufacture.

4.9.3 Storing ability: The cheese should normally maintain its characteristics for a minimum of 1 month at a temperature of 15° C from the time it is ready for consumption.

5. *Method of manufacture.*

5.1 Method of coagulation: Rennet or other suitable coagulating enzymes.

5.2 Heat treatment: After cutting the curd to particles about the size of wheat grains, heating to 50° C as a minimum.

5.3 Fermentation procedure: Lactic acid fermentation and propionic acid fermentation taking place throughout the cheese at 14° C minimum for a minimum of 4 weeks.

5.4 Maturation procedure: Proteolysis due to action of enzymes of lactic acid bacteria and smear organisms at succeeding temperatures between 10° and 20° C.

5.5 Other principal characteristics.

5.5.1 Treatment of milk: Use of raw milk.

5.5.2 Treatment with cooking salt: The cheeses are salted by immersion in salt solution and/or dry-salted on the surface. During maturation, the surface of the cheeses is salted and smeared at intervals.

6. *Sampling and analysis.*

6.1 Sampling: According to FAO/WHO Standard B.1, "Sampling Methods for Milk and Milk Products," clause 7.2(b), "Sampling by means of a trier." Reference is made to clauses 7.2.2.1 and 7.2.2.5.

6.2 Determination of fat content: According to FAO/WHO Standard B.3, "Determination of the Fat Content of Cheese and Processed Cheese Products."

7. *Marking and labeling.* Only cheese conforming with the standard may be designated "Gruyere," "Greyerzer," or "Gruviera." It shall be labeled in conformity with the appropriate sections of Article 4 of FAO/WHO Standard A.6, "General Standard for Cheese," except that Gruyere not produced in the countries of origin must be marked with the name of the producing country even when sold on the home market.

[1] Or such other synonym (e.g., Goudycki) derived from the name Gouda as will clearly indicate this variety.

* Temporarily endorsed.

** Subject to endorsement.

STANDARD No. C-12 (1968)

INTERNATIONAL INDIVIDUAL STANDARD FOR LIMBURGER

1. *Designation of cheese:* Limburger.[1]

2. *Depositing countries:* Federal Republic of Germany, United States of America. (Country of origin: Belgium.)

3. *Raw materials.* 3.1 Kind of milk: Cow's milk.

3.2 Authorized additions.

3.2.1 Necessary additions: Cultures of harmless lactic acid producing bacteria (starter) and cultures of Bacterium linens; rennet or other suitable coagulating enzymes; and sodium chloride.

3.2.2 Optional additions: Calcium chloride, maximum 200 mg/kg of the milk used; beta carotene, maximum 600 mg/kg of the cheese; sodium and potassium nitrate, maximum 200 mg/kg of the milk used.** riboflavin (Lactoflavin); and safe and suitable enzymes to assist in flavor development.

4. *Principal characteristics of the cheese ready for consumption.*

4.1 Type.

4.1. Consistency: Soft.

4.1.2 Short description: A soft surface ripened cheese carrying a rather intensive aromatic flavor. Usually consumed at 3-6 weeks.

4.2 Shape (usual): Cubical or rectangular.

4.3 Dimensions and weight.

4.3.1 Dimensions (usual): Approximately 6x6 cm and varying in height.

4.3.2 Weight (usual): Maximum 1 kg.

4.4 Rind.

4.4.1 Consistency: Elastic.

4.4.2 Appearance: Smear developed by red and yellow smear organisms.

4.4.3 Color: Reddish-brown.

4.5 Body.

4.5.1 Texture: Soft but still sliceable.

4.5.2 Color: Ivory to yellow.

4.6 Holes.

4.6.1 Distribution: Few, irregularly distributed.

4.6.2 Shape: Irregular.

4.6.3 Size: Up to the size of a barley grain.

4.6.4 Appearance: Shiny.

4.7/4.8 Limits for fat in dry matter, moisture and dry matter contents:

Limburger

[Percent]

	A	B	C	D	E
		20	30	40	45
Minimum fat in dry matter	50	20	30	40	45
Maximum moisture content	50	65	62	58	53
Minimum dry matter content	50	35	38	42	47 47

4.9 Other principal characteristics: Typical flavor developed by red and yellow smear-producing bacteria during the ripening period of at least 2 weeks.

5. *Method of manufacture.*

5.1 Method of coagulation: Rennet or other suitable coagulating enzymes.

5.2 Heat treatment: Little or no heat applied during the manufacturing procedure.

5.3 Fermentation procedure: Lactic acid fermentation with subsequent smear development.

5.4 Maturation procedure: Ripened at 12-16° C for approximately 2 weeks.

5.5 Other principal characteristics: cheese is melted from the surface before curing or salted in brine. The rind is regularly rubbed with brine during curing.

6. *Sampling and analysis.*

6.1 Sampling: According to FAO/WHO Standard B.1, "Sampling Methods for Milk and Milk Products," clauses 7.2 (a), "Sampling by cutting," or 7.2 (c), "Taking a complete cheese as a sample."

6.2 Determination of fat content: According to FAO/WHO Standard B.3, "Determination of the Fat Content of Cheese and of Processed Cheese Products."

7. *Marking and labeling.* Only cheese conforming with this standard may be designated "Limburger"; it shall be labeled in conformity with the appropriate sections of Article 4 of FAO/WHO Standard A.6, "General Standard for Cheese."

The cheese mentioned under B, C, D, and E in 4.7 and 4.8 may be designated "Limburger" provided that the designation is accompanied by a prefix corresponding to the fat percentage, e.g., 30 percent Limburger.

STANDARD No. C-15 (1968)

INTERNATIONAL INDIVIDUAL STANDARD FOR PROVOLONE

1. *Designation of cheese:* Provolone.

2. *Depositing countries:* Italy (county or origin), United States of America.

3. *Raw materials.*

3.1 Kind of milk: Cow's milk.

3.2 Authorized additions.

3.2.1 Necessary additions: Cultures of harmless lactic acid-producing bacteria (starter); rennet (calf, lamb, or kid, liquid or paste) or other suitable coagulating enzymes; and sodium chloride.

3.2.2 Optional additions: Smoke**; hexamethylenetetramine, maximum 600 mg/kg of the liquid used to work the curd**; calcium chloride, maximum 200 kg/kg of the milk used; fast green FCF (Color Index 42053)**; brilliant blue FCF (Color Index 42090)**; indigotine FCF (Color Index 73015)**; safe and suitable enzymes to assist in flavor development; and benzoyl peroxide as a bleach.**

4. *Principal characteristics of the cheese ready for consumption.*

4.1 Type: Provolone is a "pasta filata" cheese which is used as a table or grating cheese and may be consumed either fresh or aged.

4.2 Shape: Various.

4.3 Dimensions and weights: Various.

4.4 Rind.

4.4.1 Appearance: Commonly covered with vegetable fat and/or oil, paraffin and/or plastic film.

4.4.2 Color: Natural color rind yellow to brown.

4.5 Body.

4.5.1 Texture: Fibrous or smooth.

4.5.2 Color: White to yellow straw.

4.6 Holes: A few holes and splits permitted.

4.7 Minimum fat content in the dry matter: 45 percent.

4.8 Maximum moisture content: 47 percent for unsmoked cheese; 45 percent for smoked cheese. Minimum dry matter content: 53 percent for unsmoked cheese; 55 percent for smoked cheese.

4.9 Other principal characteristics: Sweetish, buttery taste after ripening 2 to 3 months, strong or piquant taste after aging when rennet from kid is used.

5. *Method of manufacture.*

5.1 Method of coagulation: Calf's rennet for "sweet curd" and lamb or kid's rennet for "strong cheese," or other suitable coagulating enzymes.

5.2 Heat treatment of the coagulum: Curd is placed in hot water or hot whey and kneaded and stretched until smooth and free from lumps.

5.3 Fermentation procedure: The milk is subjected to the action of lactic acid produced by bacteria present in the milk or added as a starter thereto. After the proper ripening period is reached, rennet or another suitable enzyme is added to coagulate the milk.

5.4 Maturation procedure: The coagulated curd is cut, stirred, and heated to promote and regulate the separation of whey from the curd. The whey is drained off, the curd is matted and cut, immersed in hot water and kneaded and stretched until it is smooth and free from lumps. The curd is then cut and placed in molds. During molding the surface is kept warm to properly seal the surface. The molded curd is then firmed by immersion in cold water before salting.

5.5 Other principal characteristics: Cheese is salted by immersion in brine. Some shapes may be encased in ropes or twine before drying. The surface may be paraffined or waxed. The cheese may be smoked.

6. *Sampling and analysis.*

6.1 Sampling: According to FAO/WHO Standard B.1, "Sampling Methods for Milk and Milk Products," paragraph 7, "Sampling of Cheese."

6.2 Determination of fat content: According to FAO/WHO Standard B.3 "Determination of the Fat Content of Cheese and of Processed Cheese Products."

7. *Marking and labeling.* Only cheese conforming with this standard may be designated "Provolone." It shall be labeled in conformity with the appropriate sections of Article 4 of FAO/WHO Standard A.6, "General Standard for Cheese."

STANDARD No. C-7 (1966)

INTERNATIONAL INDIVIDUAL STANDARD FOR SAMSOE

1. *Designation of cheese:* Samsoe (in Danish: Samso).

2. *Depositing country:* Denmark (country of origin).

3. *Raw materials.*

3.1 Kind of milk: Cow's milk.

3.2 Authorized additions.

3.2.1 Necessary additions: Cultures of harmless lactic acid-producing bacteria (starter); rennet or other suitable coagulating enzymes; and sodium chloride.

3.2.2 Optional additions: Calcium chloride, maximum 200 mg/kg of the milk used; annatto* and beta carotene, singly or in combination, maximum 600 mg/kg of cheese; sodium and potassium nitrate, maximum 200 mg/kg of the milk used**; water; and cumin seed.

4. *Principal characteristics of the cheese ready for consumption.*

[1] Or such synonyms derived from this name as will clearly indicate this variety.

** Subject to endorsement.

** Subject to endorsement.

* Temporarily endorsed.

** Subject to endorsement.

4.1 Type (consistency): Hard.
4.2 Shape: (a) Flat cylindrical; (b) flat square; and (c) rectangular.
4.3 Dimensions and weights.
4.3.1 Dimensions: (a) Flat cylindrical: Diameter 44 cm approximately; (aa) "Mini-Samsoe": Diameter 9 cm approximately; (b) flat square: side 38 cm approximately; and (c) rectangular: Various.
4.3.2 Weights: (a) Flat cylindrical: 14 kg approximately; (aa) "Mini-Samsoe": 0.25 kg approximately; (b) flat square: 14 kg approximately; and (c) rectangular: Various.
4.4 Rind.
4.4.1 Consistency: Hard.
4.4.2 Appearance: Dry, with or without wax or plastic coating.
4.4.3 Color: Yellow.
4.5 Body.
4.5.1 Texture: Firm, suitable for cutting.
4.5.2 Color: Yellowish.
4.6 Holes.
4.6.1 Distribution: From few to plentiful, evenly distributed.
4.6.2 Shape: Round.
4.6.3 Size: Varying from pea to cherry.
4.6.4 Appearance: Smooth.
4.7/4.8 Limits for fat in dry matter, moisture and dry matter contents:

Samsoe

[Percent]

	A	B	C
		30	Mini
Minimum fat in dry matter...	45	30	45
Maximum moisture content..	44	52	48
Minimum dry matter content.....	56	48	52

4.9 Other principal characteristics: Samsoe cheese is normally not exported or sold to consumers before it is at least 6 weeks old. "Mini-Samsoe" is normally not exported or sold before it is at least 3 weeks old.
5. *Method of manufacture.*
5.1 Method of coagulation: Rennet or other suitable coagulating enzymes; addition of a lactic acid starter.
5.2 Heat treatment: Slightly heated after cutting.
5.3 Fermentation procedure: Chiefly lactic acid and slightly prepressed.
5.4 Maturation procedure: Humid to dry, at a temperature between 10° and 20° C.
5.5 Other principal characteristics: Salted, normally in brine.
6. *Sampling and analysis.*
6.1 Sampling: According to FAO/WHO Standard B.1, "Sampling Methods for Milk and Milk Products," clause 7.2(b), "Sampling by means of a trier"; reference is made to clauses 7.2.2.3 and 7.2.2.5. "Mini-Samsoe" is sampled according to clause 7.2(c), "Taking a complete cheese as a sample."
6.2 Determination of fat content: According to FAO/WHO Standard B.3, "Determination of the Fat Content of Cheese and Processed Cheese Products."
7. *Marking and labeling.* Only cheese conforming with this standard may be designated "Samsoe." It shall be labeled in conformity with the appropriate sections of Article 4 of FAO/WHO Standard A.6, "General Standard for Cheese," except that Samsoe not produced in the country of origin must be marked with the name of the producing country even when sold on the home market.

The cheese mentioned under 4.7/4.8B may be designated "Samsoe," *Provided,* That the designation is accompanied by the prefix 30 percent. The cheese mentioned under 4.3.1(aa) and 4.3.2(aa) and 4.7/4.8C may be designated "Samsoe," *Provided,* That the designation is accompanied by the prefix "Mini."

The name "30 percent Samsoe" may only be used to designate cheeses which are both manufactured and marketed in countries where it is traditional and whose legislation provides for the use of the same designation for cheeses for which different minimum fat contents are specified, *Provided,* That one of the minimum fat contents so specified is above 45 percent.

STANDARD No. C-9 (1967)

INTERNATIONAL INDIVIDUAL STANDARD FOR EMMENTALER

1. *Designation of cheese:* Emmentaler, Emmental.
2. *Depositing countries:* Switzerland (country of origin), Finland, France, United States of America.
3. *Raw materials.*
3.1 Kind of milk: Cow's milk.
3.2 Authorized additions.
3.2.1 Necessary additions: Cultures of harmless lactic acid-producing bacteria (starter) and of propionic acid producing bacteria; rennet or other suitable coagulating enzymes; sodium chloride; and water.
3.2.2 Optional additions: Calcium chloride, maximum 200 mg/kg of the milk used, and cupric sulphate, maximum 15 mg/kg cheese expressed as copper.
4. *Principal characteristics of the cheese ready for consumption.*
4.1 Type: 4A (round loaf)—Hard cheese; 4B (block)—Hard cheese; 4C (rindless block)—Hard cheese.
4.2 Shape: 4A (round loaf)—Round loaf; 4B (block)—Rectangular block; 4C (rindless block)—Rectangular block.
4.3 Dimensions and weights.
4.3.1 Height: 4A (round loaf)—12 to 30 cm; 4B (block)—12 to 30 cm; 4C (rindless block)—12 to 30 cm.
4.3.2 Diameter: 4A (round loaf)—70 to 100 cm.
4.3.3 Weight: 4A (round loaf)—minimum 50 kg; 4B (block)—minimum 30 kg; 4C (rindless block)—minimum 30 kg.
4.4 Rind.
4.4.1 Consistency: 4A (round loaf)—Hard; 4B (block)—Hard; 4C (rindless block)—Soft.
4.4.2 Appearance: 4A (round loaf)—Dry; 4B (block)—Dry; 4C (rindless block)—Like inside.
4.4.3 Color: 4A (round loaf)—Golden yellow to brown; 4B (block)—Golden yellow to brown; 4C (rindless block)—Ivory to light yellow.
4.5 Body.
4.5.1 Texture: Sliceable.
4.5.2 Color: Ivory to light yellow.
4.6 Holes.
4.6.1 Distribution: Regular, scarce to plentiful.
4.6.2 Shape: Round.
4.6.3 Diameter: Mainly 1-3 cm.
4.6.4 Appearance: Mat to brilliant.
4.7 Minimum fat content in dry matter: 45 percent.
4.8 Maximum moisture content: 40 percent. Minimum dry matter content: 60 percent.
4.9 Other principal characteristics.
4.9.1 Taste and flavor: Mild, nutlike, more or less pronounced.
4.9.2 Ready for consumption: Minimum of 60 days from day of manufacture.
4.9.3 Storing ability: The cheese should normally maintain its characteristics for a minimum of 1 month at a temperature of 15° C from the time it is ready for consumption.
5. *Method of manufacture.*
5.1 method of coagulation: Rennet or other suitable coagulating enzymes.
5.2 Heat treatment: After cutting the curd to particles about the size of wheat grains, heating to 50° C as a minimum.
5.3 Fermentation procedure: Lactic acid fermentation and propionic acid fermentation taking place throughout the cheese at 20° C minimum, for a minimum of 3 weeks.
5.4 Maturation procedure: Proteolysis due to action of microbial enzymes at succeeding temperatures between 10° and 25° C.
5.5 Other principal characteristics: Treatment with cooking salt; the cheeses are salted by immersion in salt solution and/or dry-salted on the surface; during maturation, except in the case of rindless block, the surface of the cheese is washed, cleaned and salted at intervals.
6. *Sampling and analysis.*
6.1 Sampling: According to FAO-WHO Standard B.1, "Sampling Methods for Milk and Milk Products," clause 7.2(b) "Sampling by means of a trier." Reference is made to clauses 7.2.2.1 and 7.2.2.5.
6.2 Determination of fat content: According to FAO/WHO Standard B.3, "Determination of the Fat Content of Cheese and Processed Cheese Products."
7. *Marking and labeling.* Only cheese conforming with this standard may be designated "Emmentaler" or "Emmental." It shall be labeled in conformity with the appropriate sections of Article 4 of FAO/WHO Standard A.6, "General Standard for Cheese," except that Emmentaler not produced in the country of origin must be marked with the name of the producing country even when sold on the home market.

The following discussion sets forth the significant differences between the Codex standards and U.S. standards with proposed revisions. Following each point is the Commissioner's proposed action. The Commissioner is of the opinion that the proposed changes are reasonable, will benefit international trade, and will promote honesty and fair dealing in the interest of consumers.

1. *Variable fat levels.* Codex standards for blue cheese (C-32), limburger cheese (C-12), and samsoe cheese (C-7) provide for variable fat levels within each standards. These standards require that the fat content, on a dry basis, accompany the name of the food.

The Commissioner recognizes the desirability of providing for lower-fat cheeses, thus giving consumers more choices in the marketplace. He therefore proposes to adopt the Codex provisions for variable fat levels for blue cheese limburger cheese, and samsoe cheese. In addition, he is aware that cheddar cheese and swiss cheese having higher moisture and lower fat

levels than provided for in the existing standards for these foods are currently produced and marketed in the United States as "imitation" foods. Therefore, he also is proposing variable fat levels for these cheeses. If interest in providing for variable fat levels in the other cheese standards included in this proposal exists, the Commissioner would like to receive comments to this effect, accompanied by information and/or data in support of suggested fat levels for each cheese. Elsewhere in this document the Commissioner is proposing that a declaration of milk fat content, by weight, accompany the name of the food.

2. *Optional ingredients.* Many of the Codex standards provide for the use of such optional ingredients as sodium and potassium nitrates, sodium dihydrogen phosphate, disodium hydrogen phosphate, cupric sulfate, and hexamethylenetetramine.

The Commissioner is unaware of the need in cheese manufacturing practice in the United States for the above-named chemicals.

The Codex standards list all permitted optional ingredients individually, rather than by a functional group designation.

The Commissioner believes that the proposed revision of the U.S. standards to provide for the use of functional groups of safe and suitable ingredients rather than individually naming each approved ingredient from the functional group simplifies the standards and eliminates the need to amend the standards each time a food additive petition is submitted and approved which is applicable to a standard of identity for a cheese variety.

3. *Minimum milk fat and maximum moisture levels.* In certain instances, the minimum milk fat or maximum moisture levels permitted by the Codex standards differ from those in the U.S. standards.

Wherever the minimum, milk fat level is higher in the Codex standard than in the corresponding U.S. standard, the Commissioner is proposing retention of the latter. The Commissioner understands that milk now produced in the United States is not as high in milk fat as the milk of several years ago. To meet higher milk fat minimums, cheese manufacturers would have to use increased amounts of milk fat, the higher cost being borne by consumers. Since consumer interest seems to be directed to lower-fat foods and the minimum milk fat levels specified in the U.S. standards would not hinder a manufacturer from producing a higher-fat cheese, the Commissioner finds no justification for proposing acceptance of the higher milk fat minimums set by the Codex standards.

Further, the Commissioner is not proposing to accept Codex maximum moisture levels where such levels are higher. He believes this action would have the effect of lowering the quality of the cheeses, because water would displace more valuable constitutents such as milk fat and milk solids-not-fat.

4. *Phenol equivalent value.* The Codex standards do not include maximum phenol equivalent values to be used as indicators of effective pasteurization.

As discussed earlier, the Commissioner proposes to retain or to provide for maximum allowable phenol equivalent values in each standard. When pasteurized milk products are used, he is of the opinion that the phenol equivalent value, as determined by the phosphatase test described in the proposed § 133.5, serves as an indicator of effective pasteurization procedures.

In a notice published in the FEDERAL REGISTER of June 9, 1978 (43 FR 25296), the Food and Drug Administration, the U.S. Department of Agriculture, and the Federal Trade Commission announces a series of five public hearings to discuss several issues related to food labeling, including ingredient labeling, nutrition labeling, and imitation foods. The last of these hearings is scheduled for October 25-26, 1978. Because the Commissioner intends to take into consideration all relevant information presented at the hearings in developing a regulation based upon this proposal, the Commissioner has scheduled the comment period on this proposal to extend beyond the last of the hearings; comments may be sumbitted on or before November 27, 1978.

The Commissioner proposes that all products initially introduced into interstate commerce on or after 1 year following the date of issuance of a regulation based upon this proposal shall comply with the regulation, except for any provisions that may be stayed by the filing of proper objections.

The Commissioner has considered the environmental effects of the issuance or amendment of food standards and has concluded in § 25.1(d)(4) (21 CFR 25.1(d)(4)) that food standards are not major agency actions significantly affecting the quality of the human environment. Therefore, an environmental impact statement is not required for this amendment.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 401, 701(e), 52 Stat. 1046 as amended, 70 Stat. 919 as amended (21 U.S.C. 341, 371(e))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes that part 133 be amended as follows:

1. By revising § 133.3 to read as follows:

§ 133.3 Definitions.

(a) "Milk" means the lacteal secretion, practically free from colostrum, obtained by the complete milking of one or more healthy cows; concentrated milk, reconstituted milk, and dry whole milk. Water, in a sufficient quantity to reconstitute concentrated and dry forms, may be added.

(b) "Nonfat milk" means skim milk, concentrated skim milk, reconstituted skim milk, and nonfat dry milk. Water, in a sufficient quantity to reconstitute concentrated and dry forms, may be added.

(c) "Cream" means cream, reconstituted cream, dry cream, and plastic cream. Water, in a sufficient quantity to reconstitute concentrated and dry forms, may be added.

(d) "Pasteurized" when used to describe a dairy ingredient means that every particle of such ingredient shall have been heated in properly operated equipment to one of the temperatures specified in the table of this paragraph and held continuously at or above that temperature for the specified time (or other time/temperature relationship which has been demonstrated to be eqivalent thereto in microbial destruction):

Temperature:	*Time*
145° F[1]	30 min.
161° F[1]	15 s.
191° F	1 s.
204° F	0.05 s.
212° F	0.01 s.

[1]If the dairy ingredient has a fat content of 10 percent or more, the specified temperature shall be increased by 5° F.

(e) "Ultrapasteurized" when used to describe a dairy ingredient means that such ingredient shall have been thermally processed at or above 280° F for at least 2 seconds.

2. By adding new § 133.5, to read as follows:

§ 133.5 Methods of analysis.

Moisture, milk fat, and phosphatase levels in cheeses will be determined by the following methods of analysis from "Official Methods of Analysis of the Association of Official analytical Chemists," 12th ed., 1975.[2]

(a) Moisture content—"Moisture, Method I—Official Final Action," § 16.217.

(b) Milk fat content—"Fat—Official Final Action," § 16.230.

(c) Phenol equivalent value—"Residual Phosphatase—Official Final Action," § 16.245.

3. By revising § 133.106, to read as follows:

§ 133.106 Blue cheese.

(a) *Description.* (1) Blue cheese is the food prepared by the procedure

[2]Copies may be obtained from the Association of Official Analytical Chemists, P.O. Box 540, Benjamin Franklin Station, Washington, D.C. 20044.

set forth in paragraph (a)(4) of this section, or by any other procedure which produces a finished cheese having the same physical and chemical properties. It is characterized by the presence of bluish-green mold throughout the cheese. The minimum milk fat and maximum moisture contents, by weight, shall conform to any one of the fat/moisture combinations in paragraph (a)(2) of this section. Each minimum fat/maximum moisture content combination will result in the maximum percent moisture on a fat-free basis by weight, and minimum percent total solids by weight, indicated. The dairy ingredients used may be pasteurized. Blue cheese is at least 60 days old.

(2) Any one of the following minimum milk fat/maximum moisture combinations may be used:

[Figures in percent]

Minimum fat	31	26	20
Maximum moisture	48	48	55
Moisture on a fat-free basis	70	65	69
Total solids	52	52	45

(3) If pasteurized dairy ingredients are used, the phenol equivalent value of 0.25 gram of blue cheese is not more than 3 micrograms as determined by the method described in § 133.5.

(4) One or more of the dairy ingredients specified in paragraph (b)(1) of this section may be bleached, warmed, and is subjected to the action of a lactic acid-producing bacterial culture. One or more of the clotting enzymes specified in paragraph (b)(2) of this section is added to set the dairy ingredients to a semisolid mass. The mass is cut into smaller portions and allowed to stand for a time. The mixed curd and whey is placed in forms permitting further drainage. While being placed in forms, spores of the mold *Penicillium roquefortii* are added. The forms are turned several times during drainage. When sufficiently drained, the shaped curd is removed from the forms and salted with dry salt or brine. Perforations are then made in the shaped curd, and it is held at a temperature of approximately 50° F, at 90 to 95 percent relative humidity, until the characteristic mold growth has developed. During storage the surface of the cheese may be scraped to remove surface growth of undesirable microorganisms. Antimycotics may be applied to the surface of the whole cheese. One or more of the other optional ingredients specified in paragraph (b)(3) of this section may be added during the procedure.

(b) *Optional ingredients.* The following safe and suitable ingredients may be used:

(1) *Dairy ingredients.* Milk, nonfat milk, or cream, as defined in § 133.3, used alone or in combination.

(2) *Clotting enzymes.* Rennet and/or other clotting enzymes of animal, plant, or microbial origin.

(3) *Other optional ingredients.* (i) Blue or green color in an amount to neutralize the natural yellow color of the curd.

(ii) Calcium chloride in an amount not more than 0.02 percent (calculated as anhydrous calcium chloride) of the weight of the dairy ingredients, used as a coagulation aid.

(iii) Enzymes of animal, plant, or microbial origin, used in curing or flavor development.

(iv) Antimycotic agents, applied to the surface of slices or cuts in consumer-sized packages or to the surface of the bulk cheese during curing.

(v) Benzoyl peroxide or a mixture of benzoyl peroxide with potassium alum, calcium sulfate, and magnesium carbonate used to bleach the dairy ingredients. The weight of the benzoyl peroxide is not more than 0.002 percent of the weight of the milk being bleached, and the weight of the potassium alum, calcium sulfate, and magnesium carbonate, singly or combined, is not more than six times the weight of the benzoyl peroxide used. If milk is bleached in this manner, vitamin A is added to the curd in such quantity as to compensate for the vitamin A or its precursors destroyed in the bleaching process, and artificial coloring is not used.

(c) *Nomenclature.* (1) The name of the food is "blue cheese."

(2) The following phrase, in letters not less than one-half the height of the letters used in the name of the food, shall accompany the name of the food wherever it appears on the principal display panel or panels: "Contains —% fat", the blank being filled in with the whole number closest to the actual fat content, by weight, of the food.

(d) *Label declaration.* The common or usual name of each of the ingredients used in the food shall be declared on the label as required by the applicable sections of part 101 of this chapter, except that:

(1) Enzymes of animal, plant, or microbial origin may be declared as "enzymes"; and

(2) The dairy ingredients may be declared, in descending order of predominance, by the use of the terms "milkfat and nonfat milk" or "nonfat milk and milkfat", as appropriate.

4. By revising § 133.113, to read as follows:

§ 133.113 Cheddar cheese.

(a) *Description.* (1) Cheddar cheese is the food prepared by the procedure set forth in paragraph (a)(4) of this section, or by any other procedure which produces a finished cheese having the same physical and chemical properties. The minimum milkfat and maximum moisture contents, by weight, shall conform to either of the fat/moisture combinations in paragraph (a)(2) of this section. Each minimum fat/maximum moisture content combination will result in the maximum percent moisture on a fat-free basis by weight, and minimum percent total solids by weight, indicated. If the dairy ingredients used are not pasteurized, the cheese is cured at a temperature of not less than 35° F for at least 60 days.

(2) Either of the following minimum milkfat/maximum moisture combinations may be used:

[Figures in percent]

Minimum fat	31	24
Maximum moisture	39	41
Moisture on a fat-free basis	57	54
Total solids	61	59

(3) If pasteurized dairy ingredients are used, the phenol equivalent value of 0.25 gram of cheddar cheese is not more than 3 micrograms as determined by the method described in § 133.5.

(4) One or more of the dairy ingredients specified in paragraph (b)(1) of this section may be warmed and is subjected to the action of a lactic acid-producing bacterial culture. One or more of the clotting enzymes specified in paragraph (b)(2) of this section is added to set the dairy ingredients to a semisolid mass. The mass is so cut, stirred, and heated with continued stirring, as to promote and regulate the separation of whey and curd. The whey is drained off, and the curd is matted into a cohesive mass. The mass is cut into slabs, which are so piled and handled as to promote the drainage of whey and the development of acidity. The slabs are then cut into pieces, which may be rinsed by sprinkling or pouring water over them, with free and continuous drainage; but the duration of such rinsing is so limited that only the whey on the surface of such pieces is removed. The curd is salted, stirred, further drained, and pressed into forms. One or more of the other optional ingredients specified in paragraph (b)(3) of this section may be added during the procedure.

(b) *Optional ingredients.* The following safe and suitable ingredients may be used:

(1) *Dairy ingredients.* Milk, nonfat milk, or cream, as defined in § 133.3, used alone or in combination.

(2) *Clotting enzymes.* Rennet and/or other clotting enzymes of animal, plant, or microbial origin.

(3) *Other optional ingredients.* (i) Coloring.

(ii) Calcium chloride in an amount not more than 0.02 percent (calculated as anhydrous calcium chloride) of the weight of the dairy ingredients, used as a coagulation aid.

(iii) Enzymes of animal, plant, or microbial origin, used in curing or flavor development.

(iv) Antimycotic agents, applied to the surface of slices or cuts in consumer-sized packages.

(c) *Nomenclature.* (1) The name of the food is "cheddar cheese".

(2) The following phrase, in letters not less than one-half the height of the letters used in the name of the food, shall accompany the name of the food wherever it appears on the principal display panel or panels: "Contains —% fat", the blank being filled in with the whole number closest to the actual fat content by weight of the food.

(d) *Label declaration.* The common or usual name of each of the ingredients used in the food shall be declared on the label as required by the applicable sections of part 101 of this chapter, except that:

(1) Enzymes of animal, plant, or microbial origin may be declared as "enzymes"; and

(2) The dairy ingredients may be declared, in descending order or predominance, by the use of the terms "milkfat and nonfat milk" or "nonfat milk and milkfat", as appropriate.

5. By revising § 133.114, to read as follows:

§ 133.114 Cheddar cheese for manufacturing.

Cheddar cheese for manufacturing conforms to the definition and standard of identity prescribed for cheddar cheese by § 133.113, except that the milk is not pasteurized, curing is not required, and the provisions of paragraph (b)(3)(iv) of that section do not apply.

6. By revising § 133.116, to read as follows:

§ 133.116 Low sodium cheddar cheese.

Low sodium cheddar cheese is the food prepared from the same ingredients and in the same manner prescribed in § 133.113 for cheddar cheese and complies with all the provisions of § 133.113, including the requirements for label statement of ingredients, except that:

(a) Salt is not used. Any safe and suitable ingredient or combination of ingredients that contains no sodium and that is recognized as a salt substitute may be used.

(b) It contains not more than 96 milligrams of sodium per pound of finished food.

(c) The name of the food is "low sodium cheddar cheese". The letters in the words "low sodium" shall be of the same size and style of type as the letters in the words "cheddar cheese", wherever such words appear on the label.

(d) If a salt substitute as provided for in paragraph (a) of this section is used, the label shall bear the statement "———— added as a salt substitute", the blank being filled in with the common name or names of the ingredient or ingredients used as a salt substitute.

(e) Low sodium cheddar cheese is subject to § 105.69 of this chapter.

7. By revising § 133.138, to read as follows:

§ 133.138 Edam cheese.

(a) *Description.* (1) Edam cheese is the food prepared by the procedure set forth in paragraph (a)(3) of this section or by any other procedure which produces a finished cheese having the same physical and chemical properties. The minimum milkfat content is 22 percent by weight, and the maximum moisture content is 45 percent by weight. At these milkfat and moisture levels, the maximum moisture on a fat-free basis will be 58 percent by weight, and the minimum total solids will be 55 percent by weight. If the dairy ingredients used are not pasteurized, the cheese is cured at a temperature of not less than than 35° for at least 60 days.

(2) If pasteurized dairy ingredients are used, the phenol equivalent value of 0.25 gram of edam cheese is not more than 3 micrograms, as determined by the method described in § 133.5.

(3) One or more of the dairy ingredients specified in paragraph (b)(1) of this section may be warmed and is subjected to the action of a lactic acid-producing bacterial culture. One or more of the clotting enzymes specified in paragraph (b)(2) of this section is added to set the dairy ingredients to a semisolid mass. After coagulation the mass is cut into small cube-shaped pieces with sides approximately three-eighths-inch long. The mass is stirred and heated to about 90° F, and so handled by further stirring, heating, dilution with water or salt brine, and salting as to promote and regulate the separation of curd and whey. When the desired curd is obtained, it is transferred to forms permitting drainage of whey. During drainage the curd is pressed and turned. After drainage the curd is removed from the forms and is salted and cured. One or more of the other optional ingredients specified in paragraph (b)(3) of this section may be added during the procedures.

(b) *Optional ingredients.* The following safe and suitable ingredients may be used:

(1) *Dairy ingredients.* Milk, nonfat milk, or cream, as defined in § 133.3, used alone or in combination.

(2) *Clotting enzymes.* Rennet and/or other clothing enzymes of animal, plant, or microbial origin.

(3) *Other optional ingredients.* (i) Coloring.

(ii) Calcium chloride in an amount not more than 0.02 percent (calculated as anhydrous calcium chloride) of the weight of the dairy ingredients, used as a coagulation aid.

(iii) Enzymes of animal, plant, or microbial origin, used in curing or flavor development.

(iv) Antimycotic agents, applied to the surface of slices or cuts in consumer-sized packages.

(c) *Nomenclature.* (1) The name of the food is "edam cheese."

(2) The following phrase, in letters not less than one-half the height of the letters used for the name of the food, shall accompany the name of the food wherever it appears on the principal display panel of panels: "Contains — percent fat," the blank being filled in with the whole number closest to the actual fat content, by weight, of the food.

(d) *Label declaration.* The common or usual name of each of the ingredients used in the food shall be declared on the label as required by the applicable sections of part 101 of this chapter, except that:

(1) Enzymes of animal, plant, or microbial origin may be declared as "enzymes"; and

(2) The dairy ingredients may be declared, in descending order of predominance, by the use of the terms "milkfat and nonfat milk" or "nonfat milk and milkfat," as appropriate.

8. By revising § 133.142, to read as follows:

§ 133.142 Gouda cheese.

Gouda cheese conforms to the definition and standard of identity and complies with the requirements for label declaration of ingredients prescribed for edam cheese by § 133.138, except that the minimum milkfat content is 25 percent by weight and the maximum moisture content is 45 percent by weight. At these milkfat and moisture levels, the maximum moisture on a fat-free basis will be 60 percent by weight, and the minimum total solids will be 55 percent by weight.

9. By revising § 133.149, to read as follows:

§ 133.149 Gruyere cheese.

(a) *Description.* (1) Gruyere cheese is the food prepared by the procedure set forth in paragraph (a)(3) of this section or by any other procedure which produces a finished cheese having the same physical and chemical properties. It contains small holes or eyes. It has a mild flavor, due in part to the growth of surface-curing agents. The minimum milkfat content is 27 percent by weight, and the maxi-

mum moisture content is 39 percent by weight. At these milkfat and moisture levels, the maximum moisture on a fat-free basis will be 53 percent by weight, and the minimum total solids will be 61 percent by weight. The dairy ingredients used may be pasteurized. The cheese is at least 90 days old.

(2) If pasteurized dairy ingredients are used, the phenol equivalent value of 0.25 gram of gruyere cheese is not more than 3 micrograms as determined by the method described in § 133.5.

(3) One or more of the dairy ingredients specified in paragraph (b)(1) of this section may be warmed and is subjected to the action of lactic acid-producing and propionic acid-producing bacterial cultures. One or more of the clotting enzymes specified in paragraph (b)(2) of this section is added to set the dairy ingredients to a semisolid mass. The mass is cut into particles similar in size to wheat kernels. For about 30 minutes the particles are alternately stirred and allowed to settle. The temperature is raised to about 126° F. Stirring is continued until the curd becomes firm. The curd is transferred to hoops or forms, and pressed until the desired shape and firmness are obtained. The cheese is surface-salted while held at a temperature of 48° to 54° F for a few days. It is soaked for 1 day in a saturated salt solution. It is then held for 3 weeks in a salting cellar and wiped every 2 days with brine cloth to insure growth of biological curing agents on the rind. It is then removed to a heating room and held at progressively higher temperatures, finally reaching 65° F with a relative humidity of 85 to 90 percent, for several weeks, during which time small holes, or so-called eyes, form. The cheese is then stored at a lower temperature for further curing. One or more of the other optional ingredients specified in paragraph (b)(3) of this section may be added during the procedure.

(b) *Optional ingredients.* The following safe and suitable ingredients may be used:

(1) *Dairy ingredients.* Milk, nonfat milk, or cream, as defined in § 133.3, used alone or in combination.

(2) *Clotting enzymes.* Rennet and/or other clotting enzymes of animal, plant, or microbial origin.

(3) *Other optional ingredients.* (i) Calcium chloride in an amount not more than 0.002 percent (calculated as anhydrous calcium chloride) of the weight of the dairy ingredients, used as a coagulation aid.

(ii) Enzymes of animal, plant, or microbial origin, used in curing or flavor development.

(iii) Antimycotic agents, applied to the surface of slices or cuts in consumer-sized packages.

(c) *Nomenclature.* (1) The name of the food is "Gruyere cheese".

(2) The following phrase, in letters not less than one-half the height of the letters used in the name of the food, shall accompany the name of the food wherever it appears on the principal display panel or panels: "Contains —% fat", the blank being filled in with the whole number closest to the actual fat content, by weight, of the food.

(d) *Label declaration.* The common or usual name of each of the ingredients used in the food shall be declared on the label as required by the applicable sections of part 101 of this chapter, except that:

(1) Enzymes of animal, plant, or microbial origin may be declared as "enzymes"; and

(2) The dairy ingredients may be declared, in descending order of predominance, by the use of the terms "milkfat and nonfat milk" or "nonfat milk and milkfat", as appropriate.

10. By revising § 133.152, to read as follows:

§ 133.152 Limburger cheese.

(a) *Description.* (1) Limburger cheese is the food prepared by one of the procedures set forth in paragraph (a)(4) of this section, or by any other procedure which produces a finished cheese having the same physical and chemical properties. The minimum milkfat and maximum moisture contents, by weight, shall conform to any one of the fat/moisture combinations in paragraph (a)(2) of this section. Each minimum fat/maximum moisture content combination will result in the maximum percent moisture on a fat-free basis by weight, and minimum percent total solids by weight, indicated. If the dairy ingredients used are not pasteurized, the cheese is cured at a temperature of 35° F for at least 60 days.

(2) Any one of the following minimum milkfat/maximum moisture combinations may be used.

[Figures in percent]

Minimum fat	25	21	17	11	7
Maximum moisture	50	53	58	62	65
Moisture on a fat-free basis	67	67	70	70	70
Total solids	50	47	42	38	35

(3) If pasteurized dairy ingredients are used, the phenol equivalent value of 0.25 gram of Limburger cheese is not more than 4 micrograms as determined by the method described in § 133.5.

(4) One of the following procedures may be followed for producing Limburger cheese:

(i) One or more of the dairy ingredients, unpasteurized, specified in paragraph (b)(1) of this section is warmed to about 92° F and subjected to the action of a lactic acid-producing bacterial culture. One or more of the clotting enzymes specified in paragraph (b)(2) of this section is added to set the dairy ingredients to a semisolid mass. The mass is cut into cubes with sides approximately one-half inch long. After a few minutes the mass is stirred and heated, gradually raising the temperature to 96° to 98° F. The curd is then allowed to settle, most of the whey is drained off, and the remaining curd and whey dipped into molds. During drainage the curd may be pressed. It is turned at regular intervals. After drainage the curd is cut into pieces of desired size and dry-salted at intervals for 24 to 48 hours. The cheese is then cured with frequent applications of a weak brine solution to the surface, until the proper growth of surface-curing organisms is obtained. It is then wrapped and held in storage for development of as much additional flavor as is desired. One or more of the other optional ingredients specified in paragraph (b)(3) of this section may be added during the procedure.

(ii) One or more of the dairy ingredients specified in paragraph (b)(1) of this section is pasteurized, brought to a temperature of 89° to 90° F after pasteurization, and is subjected to the action of a lactic acid-producing bacterial culture. The procedure is then the same as in paragraph (a)(4)(i) of this section, except that heating is to 94° F. After most of the whey is drained off, salt brine at a temperature of 66° to 70° F is added, so that the pH of the curd is about 4.8. The mixed curd, whey, and brine is dipped into molds, and the remaining procedure specified in paragraph (a)(1)(i) of this section is followed.

(b) *Optional ingredients.* The following safe and suitable ingredients may be used:

(1) *Dairy ingredients.* Milk, nonfat milk, or cream, as defined in § 133.3, used alone or in combination.

(2) *Clotting enzymes.* Rennet and/or other clotting enzymes of animal, plant, or microbial origin.

(3) *Other optional ingredients.* (i) Coloring.

(ii) Calcium chloride in an amount not more than 0.02 percent (calculated as anhydrous calcium chloride) by weight of the dairy ingredients, used as a coagulation aid.

(iii) Enzymes of animal, plant, or microbial origin, used in curing or flavor development.

(c) *Nomenclature.* (1) The name of the food is "Limburger cheese".

(2) The following phrase, in letters not less than one-half the height of the letters used in the name of the food, shall accompany the name of the food wherever it appears on the principal display panel or panels: "Contains —% fat", the blank being filled in with

the whole number closest to the actual fat content, by weight, of the food.

(d) *Label declaration.* The common or usual name of each of the ingredients used in the food shall be declared on the label as required by the applicable sections of Part 101 of this chapter, except that:

(1) Enzymes of animal, plant, or microbial origin may be declard as "enzymes"; and

(2) The dairy ingredients may be declared, in descending order of predominance, by the use of the terms "milkfat and nonfat milk" or "nonfat milk and milkfat", as appropriate.

11. By revising § 133.181, to read as follows:

§ 133.181 Provolone cheese.

(a) *Description.* (1) Provolone, a pasta filata or stretched curd-type cheese, is the food prepared by the procedure set forth in paragraph (a)(3) of this section, or by any other method which produces a finished cheese having the same physical and chemical properties. It has a stringy texture. The minimum milkfat content is 25 percent by weight, and the maximum moisture content is 45 percent by weight. At these milkfat and moisture levels, the maximum moisture on a fat-free basis will be 60 percent by weight, and the minimum total solids will be 55 percent by weight. If the dairy ingredients used are not pasteurized, the cheese is cured at a temperature of 35° F for at least 60 days.

(2) If pasteurized dairy ingredients are used, the phenol equivalent value of 0.25 gram of Provolone cheese is not more than 3 micrograms as determined by the method described in § 133.5.

(3) One or more of the dairy ingredients specified in paragraph (b)(1) of this section may be bleached, warmed, and is subjected to the action of a lactic acid-producing bacterial culture. One or more of the clotting enzymes specified in paragraph (b)(2) of this section is added to set the dairy ingredients to a semisolid mass. The mass is cut, stirred, and heated so as to promote and regulate the separation of whey from the curd. The whey is drained off, and the curd is matted and cut, immersed in hot water, and kneaded and stretched until it is smooth and free from lumps. Antimycotics may be added to the curd during the kneading and stretching process. Then it is cut and molded. During the molding the curd is kept sufficiently warm to cause proper sealing of the surface. The molded curd is then firmed by immersion in cold water, salted in brine, and dried. It is given some additional curing. Provolone cheese may be smoked, and one or more of the other optional ingredients specified in paragraph (b)(3) of this section may be added during the procedure.

(b) *Optional ingredients.* The following safe and suitable ingredients may be used:

(1) *Dairy ingredients.* Milk, nonfat milk, or cream, as defined in § 133.3, used alone or in combination.

(2) *Clotting enzymes.* Rennet and/or other clotting enzymes of animal, plant, or microbial origin.

(3) *Other optional ingredients.* (i) Blue or green color in an amount to neutralize the natural yellow color of the curd.

(ii) Calcium chloride in an amount not more than 0.02 percent (calculated as anhydrous calcium chloride) by weight of the dairy ingredients, used as a coagulation aid.

(iii) Enzymes of animal, plant, or microbial origin, used in curing or flavor development.

(iv) Antimycotic agents, applied to the surface of slices or cuts in consumer-sized packages or added to the curd during the kneading and stretching process.

(v) Benzoyl peoxide or a mixture of benzoyl peroxide with potassium alum, calcium sulfate, and magnesium carbonate used to bleach the dairy ingredients. The weight of the benzoyl peroxide is not more than 0.002 percent of the weight of the milk being bleached, and the weight of the potassium alum, calcium sulfate, and magnesium carbonate, singly or combined, is not more than six times the weight of the benzoyl peroxide used. If milk is bleached in this manner, vitamin A is added to the curd in such quantity as to compensate for the vitamin A or its precursors destroyed in the bleaching process, and artificial coloring is not used.

(c) *Nomenclature.* (1) The name of the food is "provolone cheese". The name of the food may include the common name of the shape of the cheese, such as "salami provolone".

(2) The following words or phrases, in letters not less than one-half the height of the letters used in the name of the food, shall accompany the name of the food wherever it appears on the principal display panel or panels:

(i) "Contains —% fat", the blank being filled in with the whole number closest to the actual fat content, by weight, of the food.

(ii) "Smoked" if the food has been smoked.

(d) *Label declaration.* The common or usual name of each of the ingredients used in the food shall be declared on the label as required by the applicable sections of part 101 of this chapter, except that:

(1) Enzymes of animal, plant, or microbial origin may be declared as "enzymes"; and

(2) The dairy ingredients may be declared, in descending order of predominance, by the use of the terms "milkfat and nonfat milk" or "nonfat milk and milkfat", as appropriate.

12. By revising § 133.185, to read as follows:

§ 133.185 *Samsoe cheese.*

(a) *Description.* (1) Samsoe cheese is the food prepared by the procedure set forth in paragraph (a)(4) of this section or by any other procedure which produces a finished cheese having the same physical and chemical properties. It has a small amount of eye formation of approximately uniform size of about five-sixteenths inch (8 millimeters). The minimum milkfat and maximum moisture contents, by weight, shall conform to either of the fat/mositure combinations in paragraph (a)(2) of this section. Each minimum fat/maximum moisture content combination will result in the maximum percent moisture on a fat-free basis by weight, and minimum percent total solids by weight, indicated. The dairy ingredients used may be pasteurized. Samsoe is cured at not less than 35° F for at least 60 days.

(2) Either of the following minimum milkfat/maximum moisture combinations may be used:

[Figures in percent]

Minimum fat	27	14
Maximum moisture	41	52
Moisture on a fat-free basis	56	60
Total solids	59	48

(3) If pasteurized dairy ingredients are used, the phenol equivalent value of 0.25 gram of samsoe cheese is not more than 3 micrograms as determined by the method described in § 133.5.

(4) One or more of the dairy ingredients specified in paragraph (b)(1) of this section may be warmed and is subjected to the action of a lactic acid-producing bacterial culture. One or more of the clotting enzymes specified in paragraph (b)(2) of this section is added to set the dairy ingredients to a semisolid mass. After coagulation the mass is cut into small cube-shaped pieces with sides approximately three-eighths inch (1 centimeter). The mass is stirred and heated to about 102° F, and so handled by further stirring, heating, dilution with water, and salting as to promote and regulate the separation of curd and whey. When the desired curd is obtained, it is transferred to forms permitting drainage of whey. During drainage, the curd is pressed. After drainage, the curd is removed from the forms and is further salted by immersing in a concentrated salt solution for about 3 days. The curd is then cured at a temperature of from 60° to 70° F for 3 to 5 weeks to obtain the desired eye forma-

tion. Further curing is conducted at a lower temperature. One or more of the other optional ingredients specified in paragraph (b)(3) of this section may be added during the procedure.

(b) *Optional ingredients.* The following safe and suitable ingredients may be used:

(1) *Dairy ingredients.* Milk, nonfat milk, or cream, as defined in § 133.3, used alone or in combination.

(2) *Clotting enzymes.* Rennet and/or other clotting enzymes of animal, plant, or microbial origin.

(3) *Other optional ingredients.* (i) Coloring.

(ii) Calcium chloride in an amount not more than 0.02 percent (calculated as anhydrous calcium chloride) by weight of the dairy ingredients, used as a coagulation aid.

(iii) Enzymes of animal, plant, or microbial origin, used in curing or flavor development.

(iv) Antimycotic agents, applied to the surface of slices or cuts in consumer-sized packages.

(c) *Nomenclature.* (1) The name of the food is "Samsoe cheese".

(2) The following phrase, in letters not less than one-half the height of the letters used in the name of the food, shall accompany the name of the food wherever it appears on the principal display panel or panels: "Contains —% fat", the blank being filled in with the whole number closest to the actual fat content, by weight, of the food.

(d) *Label declaration.* The common or usual name of each of the ingredients used in the food shall be declared on the label as required by the applicable sections of part 101 of this chapter, except that:

(1) Enzymes of animal, plant, or microbial origin may be declared as "enzymes"; and

(2) The dairy ingredients may be declared, in descending order of predominance, by the use of the terms "milkfat and nonfat milk" or "notfat milk and milkfat", as appropriate.

13. By revising § 133.195, to read as follows:

§ 133.195 Swiss and emmentaler cheese.

(a) *Description.* (1) Swiss cheese, Emmentaler cheese, is the food prepared by the procedure set forth in paragraph (a)(4) of this section, or by any other procedure which produces a finished cheese having the same physical and chemical properties. It has holes or eyes developed throughout the cheese. The minimum milkfat and maximum moisture contents, by weight, shall conform to any one of the milkfat/moisture combinations in paragraph (a)(2) of this section. Each minimum fat/maximum moisture combination will result in the maximum percent moisture on a fat-free basis by weight, and minimum total solids content by weight, indicated. The dairy ingredients used may be pasteurized. Swiss cheese is at least 60 days old.

(2) Any one of the following minimum milkfat/maximum moisture combinations may be used:

[Figures in percent]

Minimum fat	25	20	15
Maximum moisture	41	44	47
Moisture on a fat-free basis	55	55	55
Total solids	59	56	53

(3) If pasteurized dairy ingredients are used, the phenol equivalent value of 0.25 gram of Swiss cheese is not more than 3 micrograms as determined by the method described in § 133.5.

(4) One or more of the dairy ingredients specified in paragraph (b)(1) of this section may be bleached, warmed, and is subjected to the action of lactic acid-producing and propionic acid-producing bacterial cultures. One or more of the clotting enzymes specified in paragraph (b)(2) of this section is added to set the dairy ingredients to a semisolid mass. The mass is cut into particles similar in size to wheat kernels. For about 30 minutes the particles are alternately stirred and allowed to settle. The temperature is raised to about 126° F. Stirring is continued until the curd becomes firm. The acidity of the whey at this point, calculated as lactic acid, does not exceed 0.13 percent. The curd is transferred to hoops or forms and pressed until the desired shape and firmness are obtained. The cheese is then salted by immersing it in a saturated salt solution for about 3 days. It is then held at a temperature of about 50° to 60° F for a period of 5 to 10 days, after which it is held at a temperature of about 75° F until it is approximately 30 days old, or until the so-called eyes form. Salt, or a solution of salt in water, is added to the surface of the cheese at some time during the curing process. The cheese is then stored at a lower temperature for further curing. One or more of the other optional ingredients specified in paragraph (b)(3) of this section may be added during the procedure.

(b) *Optional ingredients.* The following safe and suitable ingredients may be used:

(1) *Dairy ingredients.* Milk, nonfat milk, or cream, as defined in § 133.3, used alone or in combination.

(2) *Clotting enzymes.* Rennet and/or other clotting enzymes of animal, plant, or microbial origin.

(3) *Other optional ingredients.* (i) Coloring.

(ii) Calcium chloride in an amount not more than 0.02 percent (calculated as anhydrous calcium chloride) by weight of the dairy ingredients, used as a coagulation aid.

(iii) Enzymes of animal, plant, or microbial origin, used in curing or flavor development.

(iv) Antimycotic agents, applied to the surface of slices or cuts in consumer-sized packages.

(v) Benzoyl peroxide or a mixture of benzoyl peroxide with potassium alum, calcium sulfate, and magnesium carbonate used to bleach the dairy ingredients. The weight of the benzoyl peroxide is not more than 0.002 percent of the weight of the milk being bleached, and the weight of the potassium alum, calcium sulfate, and magnesium carbonate, singly or combined, is not more than six times the weight of the benzoyl peroxide used. If milk is bleached in this manner, vitamin A is added to the curd in such quantity as to compensate for the vitamin A or its precursors destroyed in the bleaching process, and artificial coloring is not used.

(c) *Nomenclature.* (1) The name of the food is "Swiss cheese", or alternatively, "Emmentaler cheese".

(2) The following phrase, in letters not less than one-half the height of the letters used in the name of the food, shall accompany the name of the food wherever it appears on the principal display panel or panels: "Contains —% fat", the blank being filled in with the whole number closest to the actual fat content, by weight, of the food.

(d) *Label declaration.* The common or usual name of each of the ingredients used in the food shall be declared on the label as required by the applicable sections of part 101 of this chapter, except that:

(1) Enzymes of animal, plant, or microbial origin may be declared as "enzymes"; and

(2) The dairy ingredients may be declared, in descending order of predominance, by the use of the terms "milkfat and nonfat milk" or "nonfat milk and milkfat", as appropriate.

14. By revising § 133.196, to read as follows:

§ 133.196 Swiss cheese for manufacturing.

Swiss cheese for manufacturing conforms to the definition and standard of identity prescribed for Swiss cheese by § 133.195, except that the holes, or eyes, have not developed throughout the entire cheese, and the provisions of paragraph (b)(3)(v) of that section do not apply; however, the labeling requirements of paragraph (d) of that section do apply.

Interested persons may, on or before November 27, 1978, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Room 4-65, 5600 Fishers Lane, Rockville, Md. 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of

comments, and shall be identified with the hearing clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

In accordance with Executive Order 12044, the economic effects of this proposal have been carefully analyzed, and it has been determined that the proposed rulemaking does not involve major economic consequences as defined by that order. A copy of the regulatory analysis assessment supporting this determination is on file with the hearing clerk, Food and Drug Administration.

Dated: September 8, 1978.

JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs.

NOTE.—Incorporation by reference provisions approved by the Director of the Office of the Federal Register on March 11, 1976. Material incorporated is on file in the FEDERAL REGISTER library.

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